

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellants: Jepson et al.
Appl. No.: 10/730,772
Conf. No.: 2213
Filed: December 8, 2003
Title: NEEDLELESS CONNECTOR
Art Unit: 3763
Examiner: Phillip A. Gray
Docket No.: MDD-5128 REI (112713-596)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on February 13, 2009. This Appeal is taken from the Final Rejection dated October 23, 2008 and the Advisory Action dated January 23, 2009.

I. REAL PARTY IN INTEREST

The real parties in interest for the above-identified patent application are Baxter International Inc. and Baxter Healthcare S.A. by virtue of an Assignment from the inventors of record, the assignment recorded on September 29, 1999, at the United States Patent and Trademark Office at reel 009589, frames 0555 to 0560.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 1 to 90 are pending in the above-identified patent application. Claims 1 to 90 are rejected and the rejection is presently appealed. A copy of the appealed claims is attached in the Claims Appendix.

IV. STATUS OF AMENDMENTS

There are no amendments pending in this case. A non-final Office Action was mailed November 30, 2007. A final Office Action was mailed on October 23, 2008. In the final Office Action, the Examiner maintained the anticipation and obviousness rejections.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the drawings and specification for each of the independent claims is provided below. In addition, a summary of the invention by way of reference to the drawings and specification for each dependent claim argued separately in the Argument section below, specifically Claims 8, 28, 35 and 55 to 78 is provided below. No claims are in means plus function format or in step plus function format.

Claim 1	Specification	Figures
1. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:	See column 8, lines 3 to 22 describing connector 300, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 17, lines 32 to 36 describing sealed interface between septum 302 of connector 300, valve 320 and penetrating member 12	FIGS. 2, 9, 10
a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing, said housing including a first upper edge portion having an outside surface of generally constant first diameter, and a second lower portion spaced from said upper edge portion and having an outside surface of a generally constant second diameter, said second diameter being larger than said first diameter, said housing including a third intermediate portion extending from said distal edge portion to said second lower portion, said third intermediate portion having an outside surface with a changing diameter;	See column 16, lines 14 to 24 describing housing 304, upper end of housing 304, opening of housing 304 and first passageway 310 formed in housing 304. See FIG. 9 illustrating upper portion (upper lip), lower portion 334 and middle portion (ramp between upper lip and 334) and respective diameters	FIGS. 9, 10
a resealable valve resiliently restrained relative to said housing, said valve including a first valve portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second valve portion integral with said first valve portion and extending generally	See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308). See FIG. 9, illustrating space between third extension portion (below crimp at valve 320,	FIGS. 9, 10

vertically downward within said passageway from a lower surface of said first valve portion, said valve having a third valve portion extending from one of said second valve portion and a lower surface of said first valve portion, a lower end portion of said third valve portion attached to said housing to form a sealed second passageway within said third valve portion, said third valve portion and said housing defining a space between said third valve portion and said housing; and	below lower portion 308) and housing portions 334/336.	
an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first valve portion, said first valve portion and said second valve portion are forced radially open by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said third valve portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.	See, column 9, lines 21 to 25 describing septum opening 316 and valve 302 attached to housing (at 346) into chamber between valve 302 and housing 334/336. See column 17, lines 25 to 32 describing septum structure such that fluid flows through extension only.	FIGS. 1, 2, 9, 10

Claim 9	Specification	Figures
9. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:	See column 8, lines 3 to 22 describing connector 300, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 17, lines 32 to 36 describing sealed interface between septum 302 of connector 300, valve 320 and penetrating member 12	FIGS. 2, 9, 10
a housing forming an upper opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;	See column 16, lines 14 to 24 describing housing 304, upper end of housing 304, opening of housing 304 and first passageway 310 formed in housing 304.	FIGS. 9, 10
a resealable valve resiliently restrained relative to said housing, said valve including,	See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308	FIGS. 9, 10

	extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308).	
a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable,	See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308).	FIGS. 9, 10
a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and	See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308).	FIGS. 9, 10
a third portion attached to said lower surface of said first portion and extending downward, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said third portion, said second portion extending within said second sealed passageway portion, said third portion and said housing defining a space between said third portion and said housing; and	See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308). See FIG. 9, illustrating space between third extension portion (below crimp at valve 320, below lower portion 308) and housing portions 334/336.	FIGS. 9, 10
an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are forcibly opened by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said third portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.	See, column 9, lines 21 to 25 describing septum opening 316 and valve 302 attached to housing (at 346) into chamber between valve 302 and housing 334/336. See column 17, lines 25 to 32 describing septum structure such that fluid flows through extension only.	FIGS. 1, 2, 9, 10

Claim 15	Specification	Figures
<p>15. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3 to 22 describing connector 300, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 17, lines 32 to 36 describing sealed interface between septum 302 of connector 300, valve 320 and penetrating member 12</p>	<p>FIGS. 2, 9, 10</p>
<p>a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;</p>	<p>See column 16, lines 14 to 24 describing housing 304, upper end of housing 304, opening of housing 304 and first passageway 310 formed in housing 304.</p>	<p>FIGS. 9, 10</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion extending from one of said second portion and a lower surface of said first portion, a lower end portion of said third portion attached to said housing to form a sealed second passageway, said valve and said housing defining a space between said valve and said housing; and</p>	<p>See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308).</p> <p>See FIG. 9, illustrating space between third extension portion (below crimp at valve 320, below lower portion 308) and housing portions 334/336.</p>	<p>FIGS. 9, 10</p>
<p>an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are radially opened by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip, the attachment of said lower end portion of said third portion to said housing being such that fluid injected from said tip flows through said housing without flowing into said space.</p>	<p>See, column 9, lines 21 to 25 describing septum opening 316 and valve 302 attached to housing (at 346) into chamber between valve 302 and housing 334/336.</p> <p>See column 17, lines 25 to 32 describing septum structure such that fluid flows through extension only.</p>	<p>FIGS. 1, 2, 9, 10</p>

Claim 21	Specification	Figures
<p>21. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3-22 describing connector 10, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 8, lines 51-58 and column 18, lines 46 to 61 describing sealed interface between valve of connector and penetrating member</p>	<p>FIGS. 2, 13, 14</p>
<p>a housing forming an upper opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;</p>	<p>See column 18, lines 59 to 67 describing housing 418, upper end 418 of housing 420, opening of housing 418 and axially extending passageway 416 formed in housing 418.</p>	<p>FIGS. 13, 14</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and a third portion extending from a lower surface of said second portion, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said third portion, at least portions of said valve and said housing defining a space between said valve and said housing; and</p>	<p>See, column 18, lines 46 to 61 describing valve 402 with upper first portion 404 middle portion 406, lower portion 410 extending from middle portion 406, lower end 417 of lower portion 410 attached to housing 418</p> <p>See column 19: lines 1 to 20 describing space between valve and housing and second passageway 416' after luer is inserted into housing 418</p>	<p>FIG. 13</p>
<p>an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion into said second portion, the luer tip opens said first portion and said second portion, forming a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that fluid injected from said tip flows through said housing without flowing into said space.</p>	<p>See column 19, lines 8-12 describing septum structure such that fluid flows through extension only and not into space between septum valve and housing.</p>	<p>FIGS. 13, 14</p>

Claim 27	Specification	Figures
<p>27. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3 to 22 describing connector 300, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 17, lines 32 to 36 describing sealed interface between septum 302 of connector 300, valve 320 and penetrating member 12</p>	<p>FIGS. 2, 9, 10</p>
<p>a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;</p>	<p>See column 16, lines 14 to 24 describing housing 304, upper end of housing 304, opening of housing 304 and first passageway 310 formed in housing 304.</p>	<p>FIGS. 9, 10</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion attached to said second portion and sealingly attached to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and</p>	<p>See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308).</p> <p>See FIG. 9, illustrating space between third extension portion (below crimp at valve 320, below lower portion 308) and housing portions 334/336.</p>	<p>FIGS. 9, 10</p>
<p>an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion and within said second portion, the luer tip radially opens said first portion and said second portion, forming a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that when fluid is then injected from said tip, the fluid flows through said housing without flowing into said space.</p>	<p>See, column 9, lines 21 to 25 describing septum opening 316 and valve 302 attached to housing (at 346) into chamber between valve 302 and housing 334/336.</p> <p>See column 17, lines 25 to 32 describing septum structure such that fluid flows through extension only.</p>	<p>FIGS. 1, 2, 9, 10</p>

Claim 34	Specification	Figures
<p>34. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3-22 describing connector 10, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 8, lines 51-58 and column 18, lines 46 to 61 describing sealed interface between valve of connector and penetrating member</p>	<p>FIGS. 2, 13, 14</p>
<p>a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;</p>	<p>See column 18, lines 59 to 67 describing housing 418, upper end 418 of housing 420, opening of housing 418 and axially extending passageway 416 formed in housing 418.</p>	<p>FIGS. 13, 14</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion attached to said second portion and extending downward, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said third portion, said valve and said housing defining a space between said third portion and said valve;</p>	<p>See, column 18, lines 46 to 61 describing valve 402 with upper first portion 404 middle portion 406, lower portion 410 extending from middle portion 406, lower end 417 of lower portion 410 attached to housing 418</p> <p>See column 19: lines 1 to 20 describing space between valve and housing and second passageway 416' after luer is inserted into housing 418</p>	<p>FIG. 13</p>
<p>a collapsing member connected to the third portion and located in the annular space; and</p>	<p>See, column 19, lines 29-37 describing collapsing member 452, split collar 454, landings 458</p>	<p>FIG. 15</p>
<p>an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, the luer tip pries said first portion and said second portion open, forming a radial seal about said luer tip and allowing fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said third portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.</p>	<p>See, column 9, lines 39-51 describing septum opening 44 (slit 46). Opening 210 of FIGS. 11 and 12 correspond to opening 44 of FIG. 1.</p> <p>See column 19, lines 41-45 describing septum structure such that fluid flows through extension only and not into space between septum valve and housing.</p>	<p>FIGS. 1, 2, 15, 16</p>

Claim 40	Specification	Figures
<p>40. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3-22 describing connector 10, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 8, lines 51-58 and column 18, lines 46 to 61 describing sealed interface between valve of connector and penetrating member</p>	<p>FIG. 2, 13, 14</p>
<p>a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;</p>	<p>See column 18, lines 59 to 67 describing housing 418, upper end 418 of housing 420, opening of housing 418 and axially extending passageway 416 formed in housing 418.</p>	<p>FIGS. 13, 14</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion extending from the second portion, a lower end portion of said third portion being so oriented with respect to said housing to form a sealed second passageway, said valve and said housing defining a space between said valve and said housing; and</p>	<p>See, column 18, lines 46 to 61 describing valve 402 with upper first portion 404 middle portion 406, lower portion 410 extending from middle portion 406, lower end 417 of lower portion 410 attached to housing 418</p> <p>See column 19: lines 1 to 20 describing space between valve and housing and second passageway 416' after luer is inserted into housing 418</p>	<p>FIG. 13</p>
<p>an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are elastically opened by the luer tip to form a radial seal about said luer tip, allowing fluid to be injected from said tip into said second passageway, the lower end portion of said third portion and said housing being oriented such that fluid injected into said second passageway flows through said housing without flowing into said space.</p>	<p>See column 19, lines 8-12 describing septum structure such that fluid flows through extension only and not into space between septum valve and housing.</p>	<p>FIGS. 13, 14</p>

Claim 41	Specification	Figures
<p>41. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3 to 22 describing connector 300, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 17, lines 32 to 36 describing sealed interface between septum 302 of connector 300, valve 320 and penetrating member 12</p>	<p>FIGS. 2, 9, 10</p>
<p>a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;</p>	<p>See column 16, lines 14 to 24 describing housing 304, upper end of housing 304, opening of housing 304 and first passageway 310 formed in housing 304.</p>	<p>FIGS. 9, 10</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said second portion having an end attached to said housing such that said valve forms a sealed second passageway defining a space between said valve and said housing; and</p>	<p>See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and extending below crimp at valve 320.</p> <p>See FIG. 9, illustrating space between third extension portion (below crimp at valve 320, below lower portion 308) and housing portions 334/336.</p>	<p>FIGS. 9, 10</p>
<p>an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said luer tip radially opens said first portion and said second portion, forming a radial seal about said luer tip and allowing fluid to be injected from said tip, the attachment of said valve to said housing being such that fluid injected from said tip flows through said housing without flowing into said space.</p>	<p>See, column 9, lines 21 to 25 describing septum opening 316 and valve 302 attached to housing (at 346) into chamber between valve 302 and housing 334/336.</p> <p>See column 17, lines 25 to 32 describing septum structure such that fluid flows through extension only.</p>	<p>FIGS. 1, 2, 9, 10</p>

Claim 47	Specification	Figures
<p>47. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3 to 22 describing connector 300, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 17, lines 32 to 36 describing sealed interface between septum 302 of connector 300, valve 320 and penetrating member 12</p>	<p>FIGS. 2, 9, 10</p>
<p>a housing forming an upper opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;</p>	<p>See column 16, lines 14 to 24 describing housing 304, upper end of housing 304, opening of housing 304 and first passageway 310 formed in housing 304.</p>	<p>FIGS. 9, 10</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and a third portion attached to a lower surface of said second portion, a portion of said third portion attached to said housing to form a sealed second passageway, at least portions of said valve and said housing defining a space between said valve and said housing; and</p>	<p>See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308).</p> <p>See FIG. 9, illustrating space between third extension portion (below crimp at valve 320, below lower portion 308) and housing portions 334/336.</p>	<p>FIGS. 9, 10</p>
<p>an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion into said second portion, said first portion and said second portion are elastically forced open by the luer tip, forming a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that fluid injected from said tip does not flow into said space.</p>	<p>See, column 9, lines 21 to 25 describing septum opening 316 and valve 302 attached to housing (at 346) into chamber between valve 302 and housing 334/336.</p> <p>See column 17, lines 25 to 32 describing septum structure such that fluid flows through extension only.</p>	<p>FIGS. 1, 2, 9, 10</p>

Claim 53	Specification	Figures
<p>53. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3 to 22 describing connector 300, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 17, lines 32 to 36 describing sealed interface between septum 302 of connector 300, valve 320 and penetrating member 12</p>	<p>FIGS. 2, 9, 10</p>
<p>a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;</p>	<p>See column 16, lines 14 to 24 describing housing 304, upper end of housing 304, opening of housing 304 and first passageway 310 formed in housing 304.</p>	<p>FIGS. 9, 10</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion sealingly attached to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and</p>	<p>See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308).</p> <p>See FIG. 9, illustrating space between third extension portion (below crimp at valve 320, below lower portion 308) and housing portions 334/336.</p>	<p>FIGS. 9, 10</p>
<p>an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are elastically opened by a radial force applied by the luer tip, forming a radial seal about said luer tip, the attachment of said third portion to said housing being such that when fluid is then injected from said tip, the fluid flows through said housing without flowing into said space.</p>	<p>See, column 9, lines 21 to 25 describing septum opening 316 and valve 302 attached to housing (at 346) into chamber between valve 302 and housing 334/336.</p> <p>See column 17, lines 25 to 32 describing septum structure such that fluid flows through extension only.</p>	<p>FIGS. 1, 2, 9, 10</p>

Claim 79	Specification	Figures
<p>79. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3 to 22 describing connector 300, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 17, lines 32 to 36 describing sealed interface between septum 302 of connector 300, valve 320 and penetrating member 12</p>	<p>FIGS. 2, 9, 10</p>
<p>a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing, said housing including a first upper edge portion having an outside surface of generally constant first diameter, and a second lower portion spaced from said upper edge portion and having an outside surface of a generally constant second diameter, said second diameter being larger than said first diameter, said housing including a third intermediate portion extending between said first upper edge portion and said second portion, said third portion having an outside surface with a changing diameter;</p>	<p>See column 16, lines 14 to 24 describing housing 304, upper end of housing 304, opening of housing 304 and first passageway 310 formed in housing 304.</p> <p>See FIG. 9 illustrating upper portion (upper lip), lower portion 334 and middle portion (ramp between upper lip and 334) and respective diameters</p>	<p>FIGS. 9, 10</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first valve portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second valve portion integral with said first valve portion and extending generally vertically downward within said passageway from a lower surface of said first valve portion, said valve having a third valve portion extending from one of said second valve portion and a lower surface of said first valve portion, a lower end portion of said third valve portion abutted against said housing to form a sealed second passageway, said third valve portion and said housing defining a space between said third valve portion and said housing; and</p>	<p>See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308).</p> <p>See FIG. 9, illustrating space between third extension portion (below crimp at valve 320, below lower portion 308) and housing portions 334/336.</p>	<p>FIGS. 9, 10</p>

<p>an opening formed in said valve such that when the luer tip is inserted into said opening in said housing and through said opening, said luer tip forcibly opens said first valve portion and said second valve portion, forms a radial seal about said luer tip and allows fluid to be injected from said tip into said second passageway, the abutment of said lower end portion of said third valve portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.</p>	<p>See, column 9, lines 21 to 25 describing septum opening 316 and valve 302 attached to housing (at 346) into chamber between valve 302 and housing 334/336.</p> <p>See column 17, lines 25 to 32 describing septum structure such that fluid flows through extension only.</p>	<p>FIGS. 1, 2, 9, 10</p>
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Claim 85	Specification	Figures
<p>85. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:</p>	<p>See column 8, lines 3 to 22 describing connector 300, penetration member 12, male luer slip or luer lock 13 and luer tip 18. See column 17, lines 32 to 36 describing sealed interface between septum 302 of connector 300, valve 320 and penetrating member 12</p>	<p>FIGS. 2, 9, 10</p>
<p>a housing forming an upper end opening sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening;</p>	<p>See column 16, lines 14 to 24 describing housing 304, upper end of housing 304, opening of housing 304 and first passageway 310 formed in housing 304.</p>	<p>FIGS. 9, 10</p>
<p>a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending downward within said housing from said first portion, said valve having a third portion sealingly abutted to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and</p>	<p>See column 16, lines 14 to 32 and 42-54 describing resilient resealing member 302 with upper first portion 306 with wipeable surface, lower extension portion 308 extending from upper first portion 306, and third extension portion (below crimp at valve 320, below lower portion 308).</p> <p>See FIG. 9, illustrating space between third extension portion (below crimp at valve 320, below lower portion 308) and housing portions 334/336.</p>	<p>FIGS. 9, 10</p>
<p>an opening formed in said valve such that when the luer tip is inserted into said opening in said housing, said first portion and said second portion are radially opened by the luer tip, forming a radial seal about said luer tip,</p>	<p>See, column 9, lines 21 to 25 describing septum opening 316 and valve 302 attached to housing (at 346) into chamber between valve 302 and housing 334/336.</p> <p>See column 17, lines 25 to 32 describing</p>	<p>FIGS. 1, 2, 9, 10</p>

the abutment of said third portion to said housing being such that when fluid is injected from said male luer tip, the fluid flows through said housing without flowing into said space.	septum structure such that fluid flows through extension only.	
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Dependent Claim 6	Specification	Figures
6. The connector device of claim 5 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.	See, column 13, lines 3-12 and 21-35 describing bonding upper landing 117 defined by upper edge 116 to valve 104 (septum 28) using bonding agent.	FIG. 4

Dependent Claims 55, 58, 61, 64, 67, 70, 73 and 76	Specification	Figures
55. The connector device of claim 15 wherein said second portion is in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 in a stretched configuration	FIG. 9
58. The connector device of claim 21 wherein said second portion is in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 in a stretched configuration	FIG. 9
61. The connector device of claim 27 wherein said second portion is in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 in a stretched configuration	FIG. 9
64. The connector device of claim 34 wherein said second portion is in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 in a stretched configuration	FIG. 9
67. The connector device of claim 40 wherein said second portion is in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 in a stretched configuration	FIG. 9
70. The connector device of claim 41 wherein said second portion is in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 in a stretched configuration	FIG. 9

73. The connector device of claim 47 wherein said second portion is in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 in a stretched configuration	FIG. 9
76. The connector device of claim 53 wherein said second portion is in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 in a stretched configuration	FIG. 9

Dependent Claims 56, 59, 62, 65, 68, 71, 74 and 77	Specification	Figures
56. The connector device of claim 15 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.	See, column 17, lines 13-20 describing extension 308 as stretched to hinder buckling when luer tip is inserted into opening.	FIG. 9
59. The connector device of claim 21 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.	See, column 17, lines 13-20 describing extension 308 as stretched to hinder buckling when luer tip is inserted into opening.	FIG. 9
62. The connector device of claim 27 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.	See, column 17, lines 13-20 describing extension 308 as stretched to hinder buckling when luer tip is inserted into opening.	FIG. 9
65. The connector device of claim 34 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.	See, column 17, lines 13-20 describing extension 308 as stretched to hinder buckling when luer tip is inserted into opening.	FIG. 9
68. The connector device of claim 40 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.	See, column 17, lines 13-20 describing extension 308 as stretched to hinder buckling when luer tip is inserted into opening.	FIG. 9
71. The connector device of claim 41 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.	See, column 17, lines 13-20 describing extension 308 as stretched to hinder buckling when luer tip is inserted into opening.	FIG. 9

74. The connector device of claim 47 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.	See, column 17, lines 13-20 describing extension 308 as stretched to hinder buckling when luer tip is inserted into opening.	FIG. 9
77. The connector device of claim 53 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.	See, column 17, lines 13-20 describing extension 308 as stretched to hinder buckling when luer tip is inserted into opening.	FIG. 9

Dependent Claims 57, 60, 63, 66, 69, 72, 75 and 78	Specification	Figures
57. The connector device of claim 15 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 as stretched during assembly and attached to the housing in a stretched configuration.	FIG. 9
60. The connector device of claim 21 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 as stretched during assembly and attached to the housing in a stretched configuration.	FIG. 9
63. The connector device of claim 27 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 as stretched during assembly and attached to the housing in a stretched configuration.	FIG. 9
66. The connector device of claim 34 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 as stretched during assembly and attached to the housing in a stretched configuration.	FIG. 9
69. The connector device of claim 40 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 as stretched during assembly and attached to the housing in a stretched configuration.	FIG. 9
72. The connector device of claim 41 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 as stretched during assembly and attached to the housing in a stretched configuration.	FIG. 9
75. The connector device of claim 47 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 as stretched during assembly and attached to the housing in a stretched configuration.	FIG. 9

78. The connector device of claim 53 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.	See, column 17, lines 13-20 describing extension 308 as stretched during assembly and attached to the housing in a stretched configuration.	FIG. 9
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Dependent Claims 28 and 35	Specification	Figures
28. The connector device of claim 27 wherein when the luer tip is inserted into the valve and fluid is injected through said tip upon removal of the luer tip, at least some fluid remaining in the second passageway is forced into the housing.	See, column 19, lines 12-21 describing fluid in chamber 416' traveling through the lower end of valve 426 upon removal of tip 18	FIG. 13, 14
35. The connector device of claim 34 wherein upon removal of the luer tip, at least some of the fluid remaining in the second passageway is forced into the housing.	See, column 19, lines 12-21 describing fluid in chamber 416' traveling through the lower end of valve 426 upon removal of tip 18	FIG. 13, 14

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations below, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,470,319 to Mayer ("*Mayer*")¹.

2. Claims 7, 14, 20, 26, 46 and 52 are rejected under 35 U.S.C. §103(a) as unpatentable in view of *Mayer*.

¹ Provided in the Evidence Appendix as Exhibit A.

VII. ARGUMENT

In summarizing the Patent Office's anticipation argument, the non-final Office Action of November 30, 2007² at Page 3 states:

The elements disclosed in Mayer are fully *capable of satisfying* all structural, functional, spatial, and operational limitations in the claims, as currently written and the rejection is made and proper. [emphasis added]

Applicants respectfully submit that merely being *capable of satisfying* all the elements does not justify an anticipation rejection, instead, to anticipate a claim, a prior art reference must *disclose* every limitation of the claimed invention, either explicitly or inherently. *Glaxo Inc. v. Novopharm Ltd.*, 34 U.S.P.Q.2D 1565, 1567 (Fed. Cir. 1995). If what the Patent Office means is that it is relying on inherency in U.S. Patent No. 5,470,319 to Mayer ("*Mayer*") to aid in making out the anticipation rejection, then the law is clear that inherency does not relieve the Patent Office of having to address each and every element of the claim. Each element, structural or functional, must be taught either explicitly or inherently, and must be done so by supplying substantial evidence. *In re Jack Richard Simpson*, 102 Fed. Appx. 675, 676 (Fed. Cir. 2004).

As set forth below, far from providing substantial evidence supporting a finding that *Mayer* teaches each structural or functional element of the claim, the non-final Office Action instead piecemeals together portions of rather differing embodiments of *Mayer* to teach certain claim elements and simply ignores others. Applicants attempted to explain these deficiencies to the Patent Office in both a personal interview performed on February 25, 2008³, and in a Response to the non-final Office Action filed April 22, 2008⁴.

Again, instead of meeting the claims element by element, in its Response to Arguments section of the final Office Action of October 23, 2008⁵, the Patent Office at Page 2 reiterated the "capable of" analysis and further stated:

² Provided in the Evidence Appendix as Exhibit B.

³ Interview Summary mailed March 4, 2008 provided in Evidence Appendix as Exhibit C.

⁴ Provided in Evidence Appendix as Exhibit D.

⁵ Provided in the Evidence Appendix as Exhibit E.

Applicant's arguments filed 4/23/2008 have been fully considered but they are not persuasive. Applicants argue that the claim language of "**the second valve portion is forced radially open by the luer tip**" is not shown in the Mayer reference. It is examiners position that when given a broad reading of the term "forced open" the Mayer reference does have a luer tip which forces open the second portion of the valve. [emphasis in original]

The final Office Action continued to gap-fill for *Mayer* by hinging its entire analysis on the "forced open" language. Moreover, while the above passage proffered that a broad interpretation of the claim language was taken, it is asserted to the contrary that it was *Mayer* that was being read broadly and indeed beyond what it might reasonably have inferred.

Applicants accordingly respectfully assert that the Patent Office's position is legally incorrect, ignores structural differences between *Mayer* and the claimed devices, and misinterprets how *Mayer* actually operates (or could operate). One example of a structural element of the claims that has been consistently ignored, is that the claimed valve has a sealed opening that is configured and positioned in combination with other elements of the claimed connector device to receive a luer tip, such that the tip actually extends through the opening and through a first portion of the valve. *Mayer* on the other hand provides a valve that in each case is configured to be opened by some mechanism other than a luer tip extending into its valve opening or septum. Each embodiment of *Mayer* not only illustrates this point explicitly, it also shows that the luer tip has in each case been extended as far into its respective housing as possible, such that the luer tip is not "capable" of extending though the opening or septum of *Mayer's* valve.

Other structural and functional differences are set forth below.

1. Claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90 are not anticipated by U.S. Patent No. 5,470,319 to Mayer (“Mayer”).

Legal Standard

35 U.S.C. §102 states that:

A patent person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

Claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90 are rejected as being anticipated by U.S. Patent No. 5,470,319 to Mayer (“Mayer”). The non-final and final Office Actions cite *Mayer* as teaching all the limitations of independent Claims 1, 9, 15, 21, 27, 34, 40, 41, 47, 53, 79 and 85. Applicants respectfully submit that there is error in the rejection of Claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90 at least because *Mayer* does not teach or suggest an opening formed in a valve, such that when a luer tip is inserted into the opening of the housing, the luer tip *extends into* the valve such that first and second portions of the valve are forcibly opened, radially opened, pried open or elastically opened by the luer tip.

Anticipation is a factual determination that “...requires the presence in a single prior art disclosure of each and every element of a claimed invention.” *Lewmar Marine, Inc. v. Barient, Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Moreover, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference.” *Verdegaal Bros. v. Union Oil of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (*emphasis added*).

Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. *See, e.g. Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364 (Fed. Cir. 2002). In this regard, a reference disclosing “substantially the same thing” is not enough to anticipate. *Jamesbury Corp. v. Litton Indust. Prod., Inc.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985). A reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found.

Further, anticipation cannot be shown by combining more than one reference to show the elements of the claimed invention. *In re Saunders*, 444 F.2d 599 (C.C.P.A. 1971). All elements of a claimed invention must be disclosed in one, solitary reference. As such, it is clear that a reference cannot be utilized to render a claimed invention anticipated without identical disclosure.

In the present application, *Mayer* does not teach each and every element of at least the claims discussed below, and therefore does not anticipate the claims. Therefore, Appellants are entitled to a patent as provided for under §102.

- (i) *Mayer* does not teach or suggest first and second valve portions forcibly opened, radially opened, pried open or elastically opened by insertion of a luer tip.

As discussed in the February 25, 2008 Examiner interview, the Response to non-final Office Action dated April 22, 2008, and the Response After Final dated December 23, 2008⁶, *Mayer* teaches a valve that is translated or distally compressed by the luer to allow a fluid pathway to open by either stretching the valve open due to the attachment of the valve to the housing or forcing the valve downward to expose a fluid pathway opening in a dilator. The present claims however set forth a different principal of operation, namely, one in which the luer tip is inserted into the valve to force or pry open an opening in the valve portion. Such arrangement provides certain advantages, such as, less dead space and more effective use of the sealing capability of the valve material within a given housing size. The present claims also specify that the resulting seal between the luer tip and the valve is a *radial* seal about the luer tip, which further structurally distinguishes the claims over *Mayer*.

Certain claims specify that the luer tip extends all the way through to the first portion of the valve and into or within a second portion of the valve. For example, “the luer tip is inserted downward into said opening in said housing and through said first portion *and within said second portion*” [emphasis added] is recited in Claim 27 and “an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and *through said first portion into said second portion*” [emphasis added] is recited in Claim 47. The final Office Action states that *Mayer*, under a broad reading of the claims, teaches, “*the second valve portion is forced radially open by the luer tip.*” See, final Office Action, page 2, “Response to

⁶ Provided in Evidence Appendix as Exhibit F.

Arguments”. As shown in detail below, the portion of the valve taken by the final Office Action to be or teach the claimed “second valve portion” is either *already* open prior to contact by the luer and thus *cannot* be opened by application of the luer, or is opened, not by the luer tip, but by interaction between the septum and other components of the device.

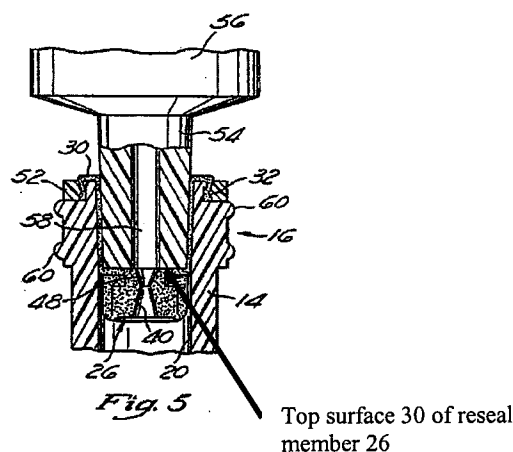
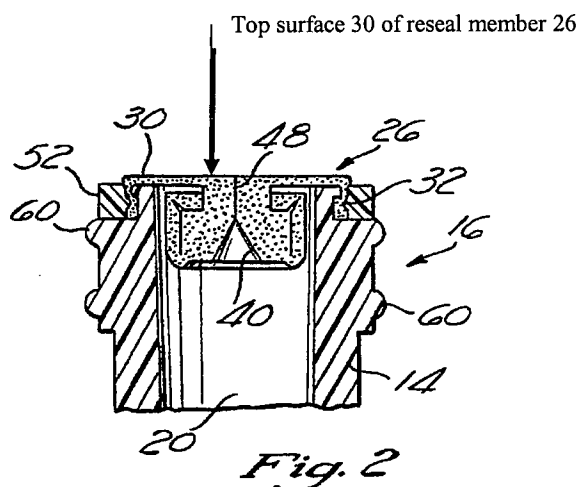
Appellants note that throughout both Office Actions, the Patent Office attempts to show anticipation by pointing to various combinations of elements over approximately three structurally distinct embodiments of *Mayer*. “[T]he prior art reference--in order to anticipate under 35 U.S.C. § 102--must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008); *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). The “arranged as in the claim” language requires an anticipatory reference “to show all of the limitations of the claims arranged or *combined in the same way* as recited in the claims.” *Net Moneyin*, 545 F.3d at 1370 (emphasis added). This does not mean that a prior art reference must disclose every element of the claim in a single embodiment. *Therasense, Inc. v. Becton, Dickinson & Co.*, 2007 U.S. Dist. LEXIS 53528, *20 (N.D. Cal. 2007). However, it is improper to pick and choose various elements that are not directly related to each other by the teachings of the reference. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083 (Fed. Cir. 2008). Instead, elements from different embodiments of a single reference can be combined for anticipation purposes only if the reference teaches or suggests such combination to one of skill in the art. *Applera Corp. v. Micromass UK Ltd.*, 204 F. Supp. 2d 724, 752 (D. Del. 2002). No support in *Mayer* or elsewhere has been provided for combining different elements from different embodiments of *Mayer* and, as set forth in the following sections, *Mayer’s* structure and operation varies substantially depending upon which embodiment is viewed. Appellants accordingly respectfully submit that the combination of structural elements from different embodiments of *Mayer* is insufficient to establish anticipation.

(ii) The First Embodiment of *Mayer*

Mayer discloses three different embodiments of valves or reseal members 26, 120 and 220. A first embodiment, illustrated in Figs. 1 to 5 (Figs. 2 and 5 shown below), shows a “reseal member 26” that, at a glance, does not teach the claims because it does not show any second or

third valve portion “attached to” (as provided in claims 1, 9, 15, 21, 27, 34, 40, 41, 47, 53) or “abutted against” (as provided in claims 79 and 85) the device housing. Nor does *Mayer* teach reseal member 26 being connected to the housing such that fluid does not flow into a space defined between the valve and housing, as generally called for in the independent claims. As seen in Figs. 2 and 5, once luer tip 54 is removed after filling housing 14 with fluid, the fluid can flow up between the outer wall of the lower portion of reseal member 26 and the inside wall of bore 20. The first embodiment does not meet the claims for this reason alone.

Further, as discussed above, none of the embodiments of *Mayer* teaches valve portions that are forcibly opened, radially opened, pried open or elastically opened by insertion of a luer tip into the slit or septum of its valve or reseal member. Figs. 2 and 5 below, including arrows added for emphasis and pointing to the top of reseal member 26, illustrate that the luer tip 54 does not enter aperture 48 at all. Again, the claims require that the luer tip extend into the opening in the valve and through a first valve portion. As seen by the arrows, the bottom of the luer tip 54 maintains contact with the top of reseal member 26 at all times and translates reseal member, as opposed to extending through it.



Regarding the Patent Office’s assertion that *Mayer* is *capable of* teaching the claims, e.g., capable of having the luer tip extend into aperture 48 and through a first portion of reseal member 26, it should be noted that luer tip 54 (as is standard) is tapered, such that the luer tip eventually becomes wedged inside bore 20, after which it cannot be inserted into the bore any further. This condition is shown in Fig. 5. That is, luer tip 54 has in Fig. 5 been inserted as far

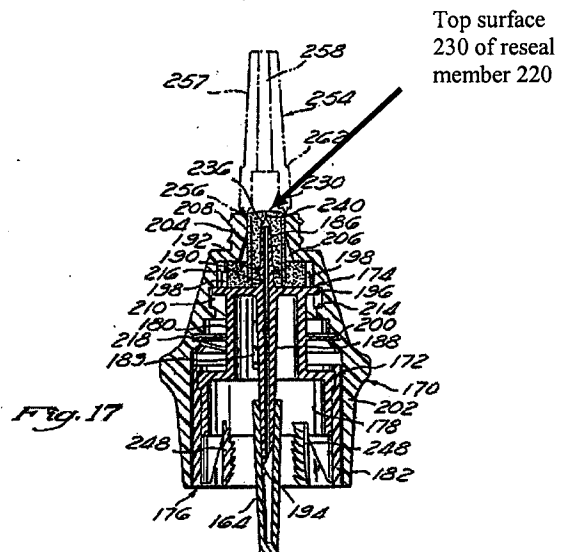
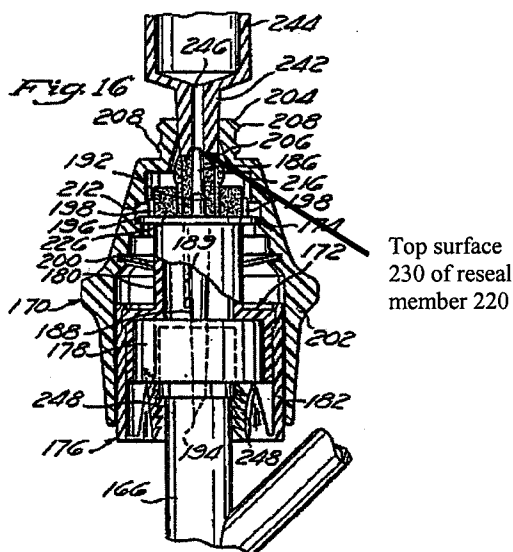
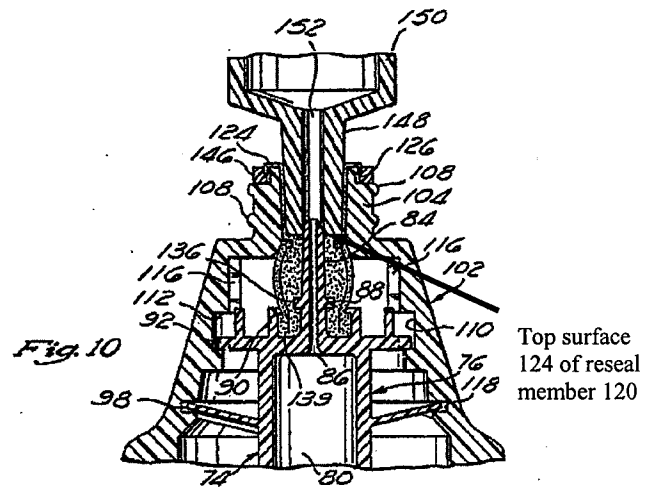
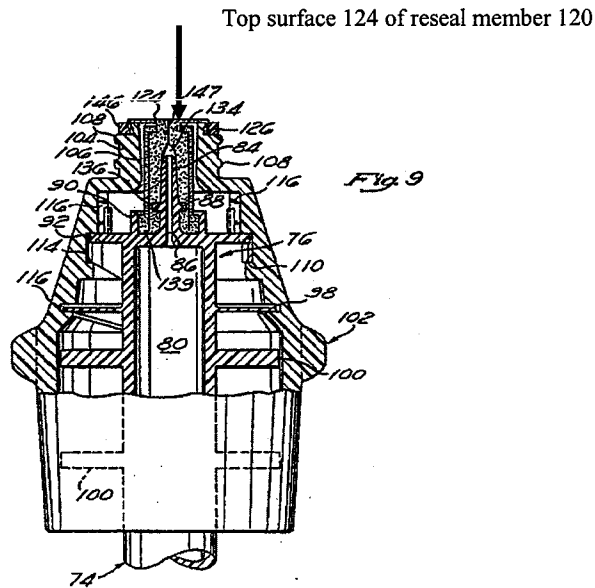
into bore 20 as it possibly can be and has not extended into aperture 48. Because luer tip 54 can extend no further into bore 20, the first embodiment of *Mayer* it is *not capable of* extending into aperture 48 to meet the claims under an inherency analysis.

(iii) The Second and Third Embodiments of *Mayer*

Figs. 6 to 10 and Figs. 14 to 17 disclose second and third embodiments, respectively, of *Mayer* (Figs. 9, 10, 16 and 17 shown below). Neither of these embodiments teaches a valve having an opening such that a luer tip extends through any upper, or first, portion of the valve such that the first valve portion is opened radially. Instead, these embodiments set forth an entirely different operation for the valve, namely, an operation requiring a separate dilator to open the valve.

In *Mayer's* description of the embodiment of Figs. 6 to 10 (see column 12, lines 64 to 67 and column 13, lines 1 to 9) and the embodiment of Figs. 14 to 17 (see column 17, lines 29 to 42), the tip 148/242 of the luer device 150/244 applies an axially directed pressure to the top surface 124/230 of the proximal valve portion 122/224, causing the reseal member 120/220 to advance translationally within the central opening 106/206, and thereby cause the aperture 142/240 to be forced over a dilator 84/184. The luer device contacts the top surface of the valve throughout the *entire* activation sequence, as shown by the arrows added for emphasis, to apply the axially directed, translational pressure. There is *no* penetration of the luer tip through any portion of the reseal member. In fact, the dilator *prevents* the male luer from extending at all *into* any portion of the valve, let alone *through* a portion of the valve. Moreover, there is no need for the luer tip to penetrate the valve because the passageway within the dilator extends upward within the tip opening to create fluid communication.

In the second and third embodiments, *Mayer* discloses nothing other than the dilator for forcing an opening of the passageway through the reseal member. Figs. 9, 10, 16 and 17 below, including arrows added for emphasis, illustrate that the luer tip does not extend *at all* through member 120/220, and instead remains in contact with top surfaces 124/230 of the respective reseal member at all times.



Regarding the embodiment of Figs. 6 to 10 and reseal member 120, the final Office Action cites element number 84 as allegedly teaching the claimed “second portion” of the claimed “resealable valve”. Element number 84 is actually the “dilator projection” of the embodiment of Figs. 6 to 10 and not any type of “second portion” of reseal member 120 as asserted in the final Office Action cites. The final Office Action therefore points to no disclosure

(because it does not exist) of a resealable valve, which allows a luer to be (i) “*within said second portion*” of the valve as recited in Claim 27 or (ii) moved “*into said second portion*” of the valve as recited in Claims 21 and 47. Claims 21, 27 and 47 accordingly recite additional patentable subject matter over *Mayer*, namely, that the luer moves all the way through the first portion of the valve and into or within the second portion of the valve. In fact, it is respectfully submitted that due to the presence of, and operation with, a dilator, *Mayer* is physically incapable of having any portion of its luer tip “inserted... within” (Claim 27) or “inserted ... into” (Claims 21 and 47) any portion of its valve.

There is likewise no possibility of a *radial seal* being formed about the luer tip by any portion of the valve of *Mayer* as called for in independent Claims 1, 9, 15, 21, 27, 34, 40, 41, 47, 53, 79 and 85. This structural element of the claims, in particular, has been given no weight in the Office Actions.

Besides the dilator preventing the second and third embodiments of *Mayer* from being “*capable of*” meeting the claims as has been asserted repeatedly in the Office Actions, it should also be noted that the luer or introducer tips 148 and 242 are again tapered, such that the tips eventually become wedged inside the respective housing bore, after which the tips physically cannot be inserted into the respective bore any further. This condition is shown for both embodiments in Figs. 10 and 16. Again, because the tips 148 and 242 can extend no further into the respective housing, the second and third embodiments of *Mayer* are additionally *not capable* of extending into the respective aperture to meet the claims under an inherency analysis.

The application of *Mayer* is additionally misguided for the following reasons. First, piercing tip 194 of *Mayer* is not a luer tip as proposed in the non-final and final Office Actions at pages 2 and 3, respectively. Second, apparatuses 176 and 202 cited as allegedly teaching the claimed “annular flange” are actually part of two different structures of the embodiment of Figs. 14 to 17 of which neither, alone or in combination, are taught by *Mayer* to provide or be an “annular flange”.

Third, Fig. 9 is cited in the Office Actions to teach the claimed “first central passageway”, while Figs. 14 to 17 are cited to teach the luer tip and the housing 170. However, these figures are from two different embodiments of *Mayer*, such that Fig. 9 has a different housing 102 than housing 170 of Figs. 14 to 17. There is no suggestion in *Mayer* of combining the different embodiments or how to combine different features of the different embodiments

even if combination is desired. And, as discussed above, such borrowing is improper for an anticipation rejection.

(iv) Mayer does not teach or suggest a second valve in a stretched configuration.

Mayer also fails to teach numerous dependent claims. For example, claims 8, 55, 58, 61, 64, 67, 70, 73 and 74 further define the second valve portion to be in a stretched configuration. Portion 84 (which we take as the valve's "second portion" for purposes of argument) of reseal member 120 of *Mayer* is never in a stretched configuration.

Claims 56, 59, 62, 65, 68, 71, 74 and 77 further define the second portion of the valve to be stretched so as to hinder buckling of said second portion when the luer tip is inserted downward into said opening. No middle or second portion of reseal member 120 of *Mayer* is ever in a stretched configuration, let alone in such a position to prevent buckling.

Claims 57, 60, 63, 66, 69, 72, 75 and 78 further define the second portion of the valve to be stretched during assembly of the connector and attached to the housing in a stretched configuration. *Mayer* does not reach these claims, and the Office Actions make no attempt to address these or any of the dependent claims listed above.

It should be appreciated that if any of the above dependent claims are addressed specifically in the Patent Office's Response to this Appeal Brief, such arguments will have been presented for the *first time*.

(v) Mayer does not teach or suggest that upon removal of the luer tip, at least some fluid remaining in the second passageway is forced into the housing.

Claims 28 and 35 also specify that upon removal of the luer tip, at least some fluid remaining in the second passageway is forced into the housing. The Office action does not even attempt to address Claims 28 and 35.

In summary, *Mayer* does not teach or suggest every limitation of Claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90. The Office Action thus fails to make out a *prima facie* rejection of Claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90. Further, many of the dependent claims have as yet not been addressed specifically. For these reasons, the rejection does not meet the legal standard set forth above in 35 U.S.C. §102(b).

Appellants accordingly respectfully submit that they are entitled to a patent at least for Claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90, that there is thus error in the rejection of these claims, and respectfully request that this Board reverse the rejections of these claims.

2. Claims 7, 14, 20, 26, 46 and 52 are not obvious in view of U.S. Patent No. 5,470,319 to Mayer ("Mayer").

Legal Standard

35 U.S.C. §103(a) states that:

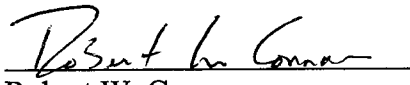
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Dependent Claims 7, 14, 20, 26, 46 and 52 are rejected as being unpatentable in view of *Mayer*. The final Office Action admits that *Mayer* fails to teach or suggest a second portion of the resealable valve formed with a generally rectangular cross section in the proximate direction. See, final Office Action, page 5. The rationale for the rejection is that it would have been an obvious matter of design choice to form the valve with a rectangular cross-section in the proximate direction, since Appellants have not disclosed that this cross-section formation solves any stated problem or is for any particular purpose, and it appears that the invention would perform equally well with a circular cross section, and in the alternative it would be within the level of ordinary skill in the art to change the circular cross section to a rectangular cross section in order to limit the flow rate by decreasing the area of the cross section (changing from a circle to rectangle). *Id.* Appellants submit that the patentability of independent Claims 1, 9, 15, 21, 27, 34, 40, 41, 47, 53, 79 and 85 renders moot the obviousness rejection of Claims 7, 14, 20, 26, 46 and 52.

The Director is authorized to charge any other fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal occurs, please indicate the Attorney Docket No. MDD-5128 REI (112713-596) on the account statement.

Respectfully submitted,

K&L GATES LLP

BY 
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Dated: March 31, 2009

CLAIMS APPENDIX

MPEP § 1454 states, “The requirements for an appeal brief are set forth in 37 CFR *41.37< and MPEP § 1206, and they apply to a reissue application in the same manner that they apply to a non-reissue application. There is, however, a difference in practice as to presentation of the copy of the claims in the appeal brief for a reissue application. The claims on appeal presented in an appeal brief for a reissue application should include *all underlining and bracketing necessary to reflect the changes made to the patent claims during the prosecution of the reissue application. In addition, any new claims added in the reissue application should be completely underlined*” (emphasis added). Appellants accordingly provide the following list of the pending claims.

1. A connector device for establishing a sealed connection with a male luer assembly [configured to conform to ISO standards], said assembly including a male luer tip, [said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip,] said connector device comprising:

a housing forming an upper end opening and a [central] first passageway sized to receive the male luer tip, said housing having an upper end portion configured to [fit within the space defined by] receive the male luer assembly when the male luer tip is inserted downward into said opening, said first [central] passageway extending from said opening in a downward direction within said housing, said housing including a first upper edge portion having an outside surface of generally constant first diameter, and a second lower portion spaced from said upper edge portion and having an outside surface of a generally constant second diameter, said second diameter being larger than said first diameter, said housing including a third intermediate portion extending from said distal edge portion to said second lower portion, said third intermediate portion having an outside surface with a changing diameter;

a resealable valve resiliently restrained relative to said housing, said valve including a first valve portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second [extension] valve portion integral with said first valve portion and extending generally vertically downward within said passageway from a lower surface of said first valve portion, said valve having a third [extension] valve portion [attached to] extending from one of said [extension] second valve portion and a lower surface of said [radial] first valve portion [and extending downward], a lower end portion of said [extension] third valve portion attached to said housing to form a sealed second passageway within said

[extension] third valve portion, said [extension] third valve portion and said housing defining a [generally annular] space between said [extension] third valve portion and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first valve portion, said first valve portion and said second valve portion [elastically extend about] are forced radially open by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said [extension] third valve portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said [annular] space.

2. The connector device of claim 1 wherein said valve includes a septum having an annular skirt attached to said first valve portion, said skirt extending over and attached to an outside surface of said housing proximate said opening.

3. The connector device of claim 2 wherein said septum includes an annular channel formed by said skirt and said first portion, a distal edge portion of said housing received in said channel.

4. The connector device of claim 3 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

5. The connector of claim 4 wherein the entire length of said landing is attached to said septum.

6. The connector device of claim 5 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

7. The connector device of claim 1 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

8. The connector device of claim 1 wherein said second [extension] valve portion is in a stretched configuration.

9. A connector device for establishing a sealed connection with a male luer assembly [configured to conform to ISO standards], said assembly including a male luer tip [and having a generally annular flange disposed generally about said male luer tip and defining a generally cylindrical space between said flange and said tip], said connector device comprising:

a housing forming an upper opening and a [central] first passageway sized to receive the male luer tip, said housing having an upper end portion configured to [fit within the generally cylindrical space defined by] receive the male luer assembly when the male luer tip is inserted downward into said opening, said first [central] passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including,

a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable,

a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and

a third [extension] portion attached to said lower surface of said first portion and extending downward, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said [extension] third portion, said second portion extending within said second sealed passageway portion, said third [extension] portion and said housing defining a [generally annular] space between said [extension] third portion and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion [elastically extend about] are forcibly opened by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said [extension] third portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said [annular] space.

10. The connector device of claim 9 which includes a septum having an annular channel formed by [said skirt and] said first portion, a distal edge portion of said housing received in said channel.

11. The connector device of claim 10 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

12. The connector of claim 11 wherein the entire length of said landing is attached to said septum.

13. The connector device of claim 12 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

14. The connector device of claim 13 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

15. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion extending from one of said second portion and a lower surface of said first portion, a lower end portion of said third portion attached to said housing to form a sealed second passageway, said valve and said housing defining a space between said valve and said housing;
and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are radially opened by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip, the attachment of said lower end portion of said third portion to

said housing being such that fluid injected from said tip flows through said housing without flowing into said space.

16. The connector device of claim 15 which includes a septum having an annular channel formed by said first portion, a distal edge portion of said housing received in said channel.

17. The connector device of claim 16 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

18. The connector of claim 17 wherein the entire length of said landing is attached to said septum.

19. The connector device of claim 18 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

20. The connector device of claim 15 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

21. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and a third portion extending from a lower surface of said second portion, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said third portion, at least

portions of said valve and said housing defining a space between said valve and said housing;
and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion into said second portion, the luer tip opens said first portion and said second portion, forming a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that fluid injected from said tip flows through said housing without flowing into said space.

22. The connector device of claim 21 which includes a septum having an annular channel formed by said first portion, a distal edge portion of said housing received in said channel.

23. The connector device of claim 22 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

24. The connector of claim 23 wherein the entire length of said landing is attached to said septum.

25. The connector device of claim 24 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

26. The connector device of claim 25 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

27. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to

be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion attached to said second portion and sealingly attached to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion and within said second portion, the luer tip radially opens said first portion and said second portion, forming a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that when fluid is then injected from said tip, the fluid flows through said housing without flowing into said space.

28. The connector device of claim 27 wherein when the luer tip is inserted into the valve and fluid is injected through said tip upon removal of the luer tip, at least some fluid remaining in the second passageway is forced into the housing.

29. The connector device of claim 27 wherein the third portion extends downwardly within the housing.

30. The connector device of claim 27 wherein the third portion is integral with the second portion.

31. The connector device of claim 27 wherein the third portion extends for a length greater than a diameter of the upper surface.

32. The connector device of claim 27 wherein the housing includes upper and lower pieces that crimp the third portion of the valve so as to be sealingly attached to said housing.

33. The connector device of claim 27 including a collapsing member located in the space.

34. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly

when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion attached to said second portion and extending downward, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said third portion, said valve and said housing defining a space between said third portion and said valve;

a collapsing member connected to the third portion and located in the annular space; and
an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, the luer tip pries said first portion and said second portion open, forming a radial seal about said luer tip and allowing fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said third portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.

35. The connector device of claim 34 wherein upon removal of the luer tip, at least some of the fluid remaining in the second passageway is forced into the housing.

36. The connector device of claim 34 wherein the collapsing member is a split collar.

37. The connector device of claim 34 wherein the third portion extends downwardly within the housing.

38. The connector device of claim 34 wherein the third portion is integral with the second portion.

39. The connector device of claim 34 wherein the third portion extends for a length greater than a diameter of the upper surface.

40. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion extending from the second portion, a lower end portion of said third portion being so oriented with respect to said housing to form a sealed second passageway, said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are elastically opened by the luer tip to form a radial seal about said luer tip, allowing fluid to be injected from said tip into said second passageway, the lower end portion of said third portion and said housing being oriented such that fluid injected into said second passageway flows through said housing without flowing into said space.

41. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said second portion having an end attached to said housing such that said valve forms a sealed second passageway defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said luer tip radially opens said first portion and said second portion, forming a radial seal about said luer tip and allowing fluid to be injected from said tip, the attachment of said valve to said housing being such that fluid injected from said tip flows through said housing without flowing into said space.

42. The connector device of claim 41 which includes a septum having an annular channel formed by a skirt and said first portion, a distal edge portion of said housing received in said channel.

43. The connector device of claim 42 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

44. The connector of claim 43 wherein the entire length of said distal landing is attached to said septum.

45. The connector device of claim 44 wherein said connector includes a bonding agent to attach said outside surface of said housing and said distal landing to said septum.

46. The connector device of claim 41 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

47. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and a third portion

attached to a lower surface of said second portion, a portion of said third portion attached to said housing to form a sealed second passageway, at least portions of said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion into said second portion, said first portion and said second portion are elastically forced open by the luer tip, forming a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that fluid injected from said tip does not flow into said space.

48. The connector device of claim 47 which includes a septum having an annular channel formed by said first portion, a distal edge portion of said housing received in said channel.

49. The connector device of claim 48 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

50. The connector of claim 49 wherein the entire length of said landing is attached to said septum.

51. The connector device of claim 50 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

52. The connector device of claim 51 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

53. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper

surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion sealingly attached to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are elastically opened by a radial force applied by the luer tip, forming a radial seal about said luer tip, the attachment of said third portion to said housing being such that when fluid is then injected from said tip, the fluid flows through said housing without flowing into said space.

54. The connector device of claim 53 wherein the third portion is integral with the second portion.

55. The connector device of claim 15 wherein said second portion is in a stretched configuration.

56. The connector device of claim 15 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

57. The connector device of claim 15 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

58. The connector device of claim 21 wherein said second portion is in a stretched configuration.

59. The connector device of claim 21 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

60. The connector device of claim 21 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

61. The connector device of claim 27 wherein said second portion is in a stretched configuration.

62. The connector device of claim 27 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

63. The connector device of claim 27 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

64. The connector device of claim 34 wherein said second portion is in a stretched configuration.

65. The connector device of claim 34 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

66. The connector device of claim 34 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

67. The connector device of claim 40 wherein said second portion is in a stretched configuration.

68. The connector device of claim 40 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

69. The connector device of claim 40 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

70. The connector device of claim 41 wherein said second portion is in a stretched configuration.

71. The connector device of claim 41 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

72. The connector device of claim 41 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

73. The connector device of claim 47 wherein said second portion is in a stretched configuration.

74. The connector device of claim 47 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

75. The connector device of claim 47 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

76. The connector device of claim 53 wherein said second portion is in a stretched configuration.

77. The connector device of claim 53 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

78. The connector device of claim 53 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

79. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing, said housing including a first upper edge portion having an outside surface of generally constant first diameter, and a second lower portion spaced from said upper edge portion and having an outside surface of a generally constant second diameter, said second diameter being larger than said first diameter, said housing including a third intermediate portion extending between said first upper edge portion and said second portion, said third portion having an outside surface with a changing diameter;

a resealable valve resiliently restrained relative to said housing, said valve including a first valve portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second valve portion integral with said first valve portion and extending generally vertically downward within said passageway from a lower surface of said first valve portion, said valve having a third valve portion extending from one of said second valve portion and a lower surface of said first valve portion, a lower end portion of said third

valve portion abutted against said housing to form a sealed second passageway, said third valve portion and said housing defining a space between said third valve portion and said housing; and an opening formed in said valve such that when the luer tip is inserted into said opening in said housing and through said opening, said luer tip forcibly opens said first valve portion and said second valve portion, forms a radial seal about said luer tip and allows fluid to be injected from said tip into said second passageway, the abutment of said lower end portion of said third valve portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.

80. The connector device of claim 79 wherein said third portion of said housing transitions from said first portion to said second portion of said housing.

81. The connector device of claim 79 wherein said lower end portion of said third valve portion is attached to said housing to form the sealed second passageway within said third portion.

82. The connector device of claim 79 wherein said space between said third valve portion and said housing is a generally annular space.

83. The connector device of claim 79 wherein at least a portion of said third portion of said valve prior to insertion of the luer tip widens towards its lower end portion.

84. The connector device of claim 79 wherein the third valve portion extends generally downwardly within said housing.

85. A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending downward within

said housing from said first portion, said valve having a third portion sealingly abutted to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted into said opening in said housing, said first portion and said second portion are radially opened by the luer tip, forming a radial seal about said luer tip, the abutment of said third portion to said housing being such that when fluid is injected from said male luer tip, the fluid flows through said housing without flowing into said space.

86. The connector device of claim 85 wherein the third portion extends generally downwardly within said housing.

87. The connector device of claim 85 wherein said third portion is attached to said housing to form the seal.

88. The connector device of claim 85 wherein said space between said third portion and said housing is a generally annular space.

89. The connector device of claim 85 wherein at least a portion of said third portion of said valve prior to insertion of the luer tip widens towards its lower end portion.

90. The connector device of claim 85 wherein the luer assembly conforms to ISO standards.

EVIDENCE APPENDIX

EXHIBIT A: U.S. Patent No. 5,470,319 to Mayer ("Mayer").

EXHIBIT B: Non-final Office Action mailed on November 30, 2007.

EXHIBIT C: Interview Summary mailed on March 4, 2008.

EXHIBIT D: Response submitted on April 22, 2008 to non-final Office Action mailed on November 30, 2007.

EXHIBIT E: Final Office Action mailed on October 23, 2008.

EXHIBIT F: Response submitted on December 23, 2008 to final Office Action mailed on October 23, 2008.

RELATED PROCEEDINGS APPENDIX

None.

Exhibit A



US005470319A

United States Patent [19]**Mayer**[11] **Patent Number:** **5,470,319**[45] **Date of Patent:** **Nov. 28, 1995**[54] **NEEDLELESS INJECTION SITE**[75] **Inventor:** **Bruno F. P. Mayer, Santa Ana, Calif.**[73] **Assignee:** **Critical Device Corporation, Brea, Calif.**[21] **Appl. No.:** **262,994**[22] **Filed:** **Jun. 20, 1994**[51] **Int. Cl.⁶** **A61M 5/00; A61M 5/178**[52] **U.S. Cl.** **604/167; 251/149.1**[58] **Field of Search** **604/167, 256; 137/850, 844; 251/149.1, 149.3, 354**[56] **References Cited****U.S. PATENT DOCUMENTS**

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Primary Examiner—Paul J. Hirsch

Attorney, Agent, or Firm—Stetina Brunda & Buyan

[57] **ABSTRACT**

A needleless injection site comprising a housing defining proximal and distal ends and including a reseal member disposed therein. The reseal member has an elastically openable and closable aperture formed therein, and normally resides within the housing in a closed position wherein the aperture is in a closed configuration. The reseal member is deformable such that the application of distally directed pressure thereto will cause the reseal member to distally advance within the housing to an open position wherein the aperture assumes an open configuration. The removal of the distally directed pressure from the reseal member will cause it to resiliently return to the closed position wherein the aperture assumes the closed configuration.

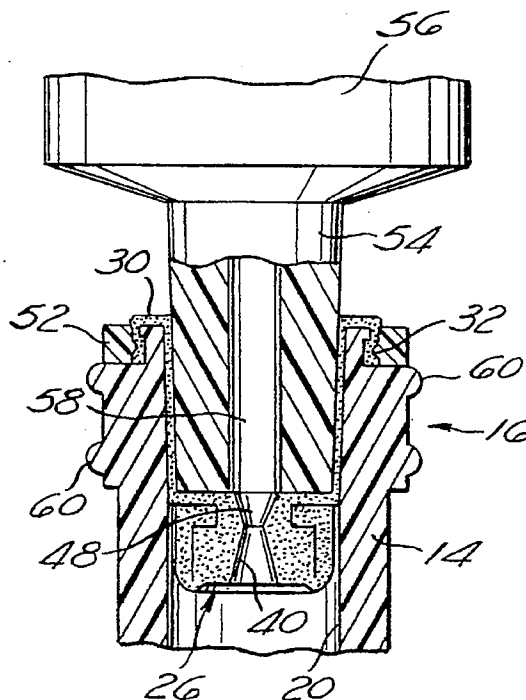
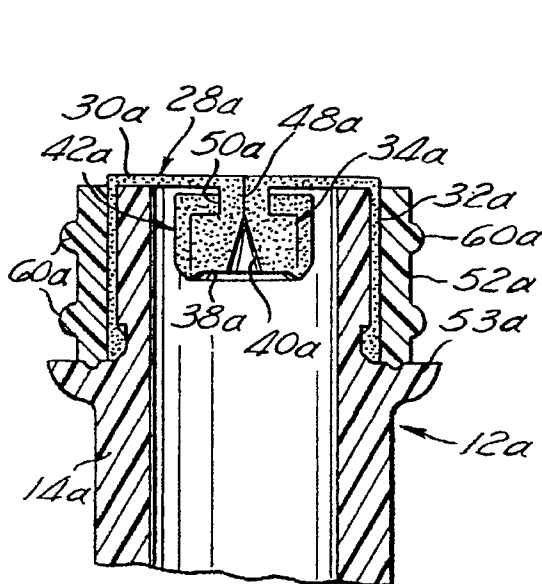
31 Claims, 5 Drawing Sheets

Fig. 1

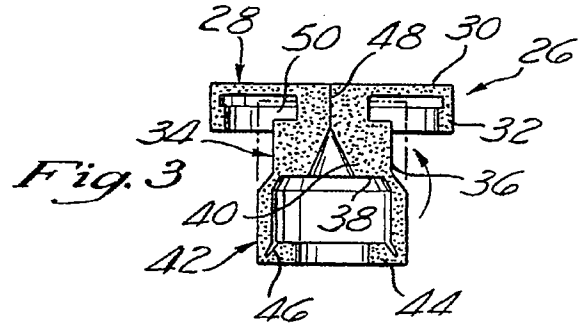
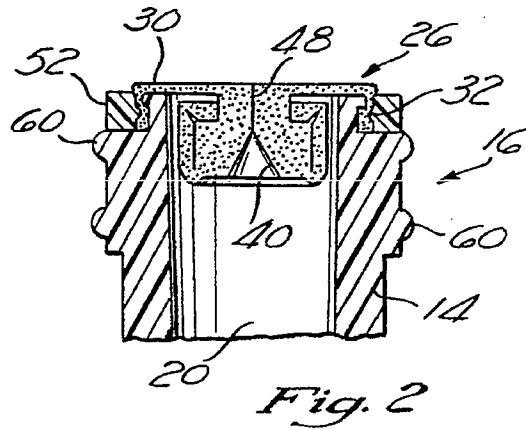
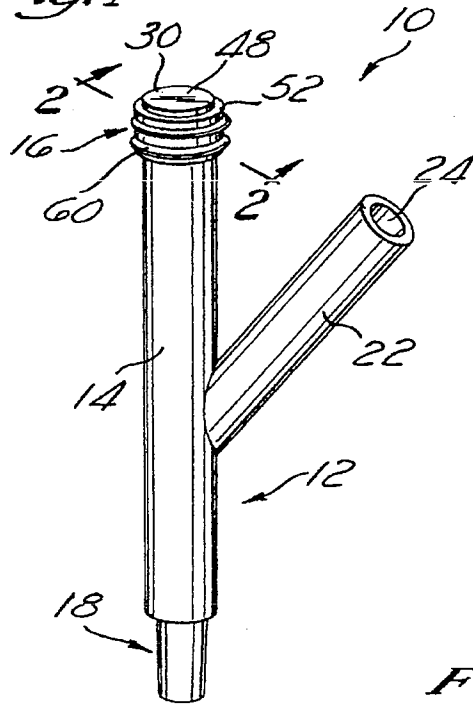


Fig. 4

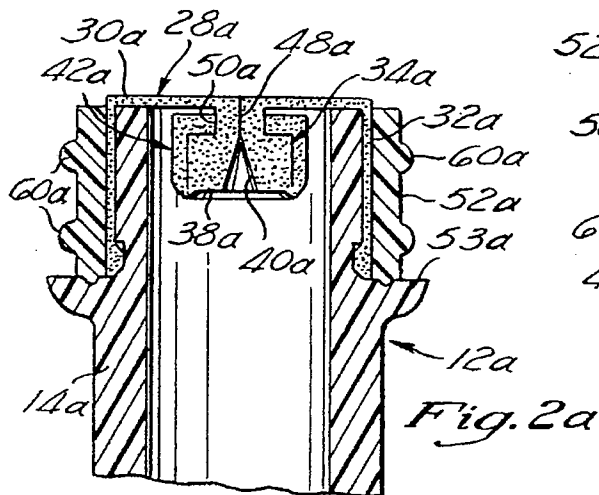
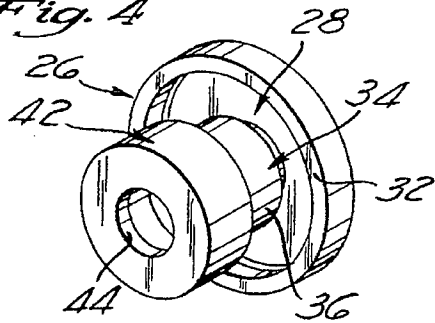


Fig. 2a

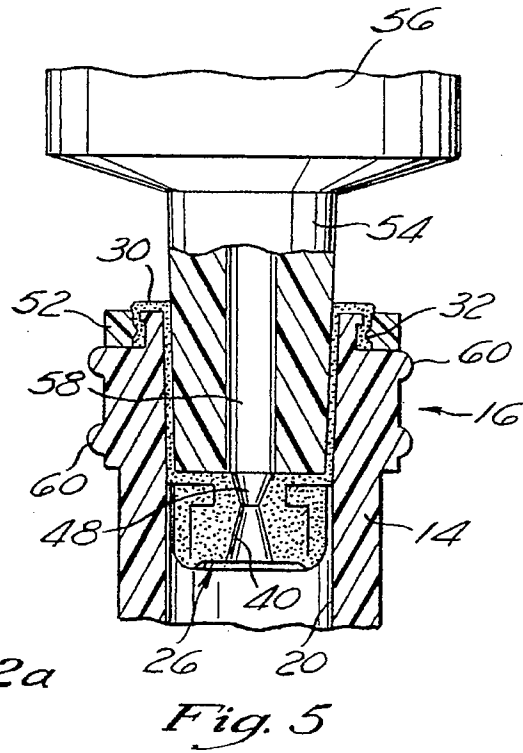


Fig. 5

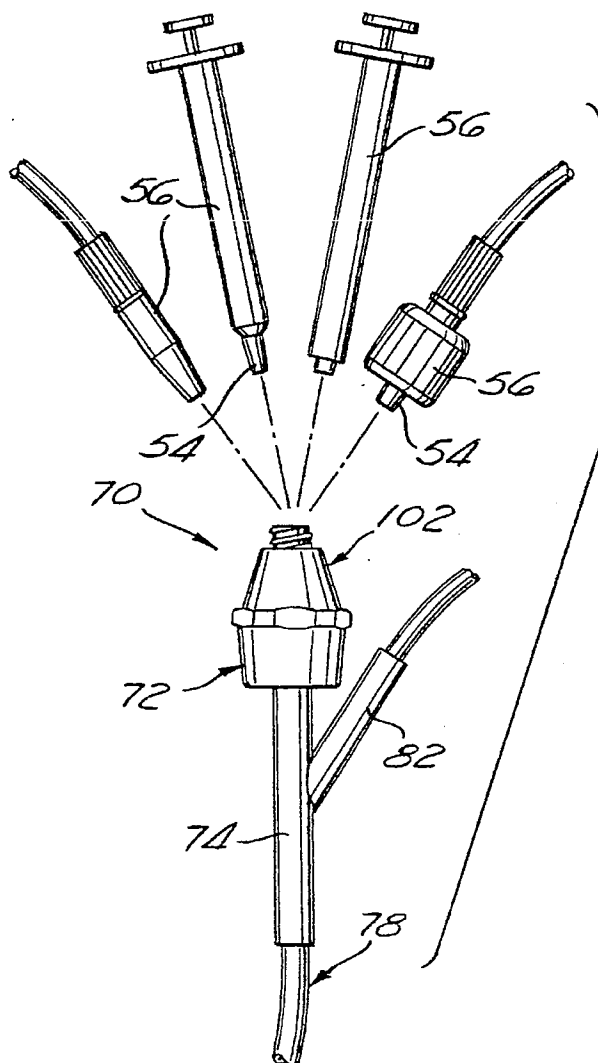


Fig. 6

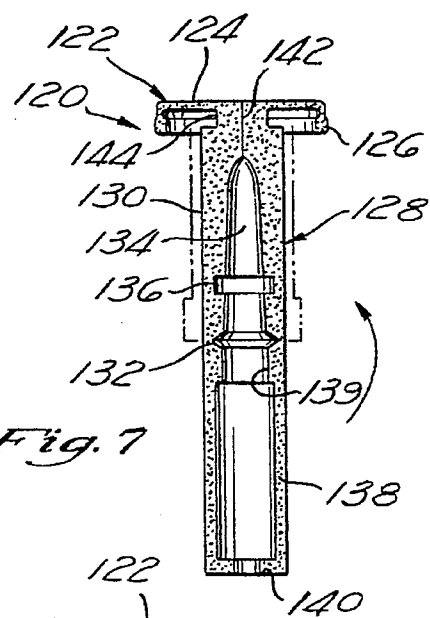


Fig. 7

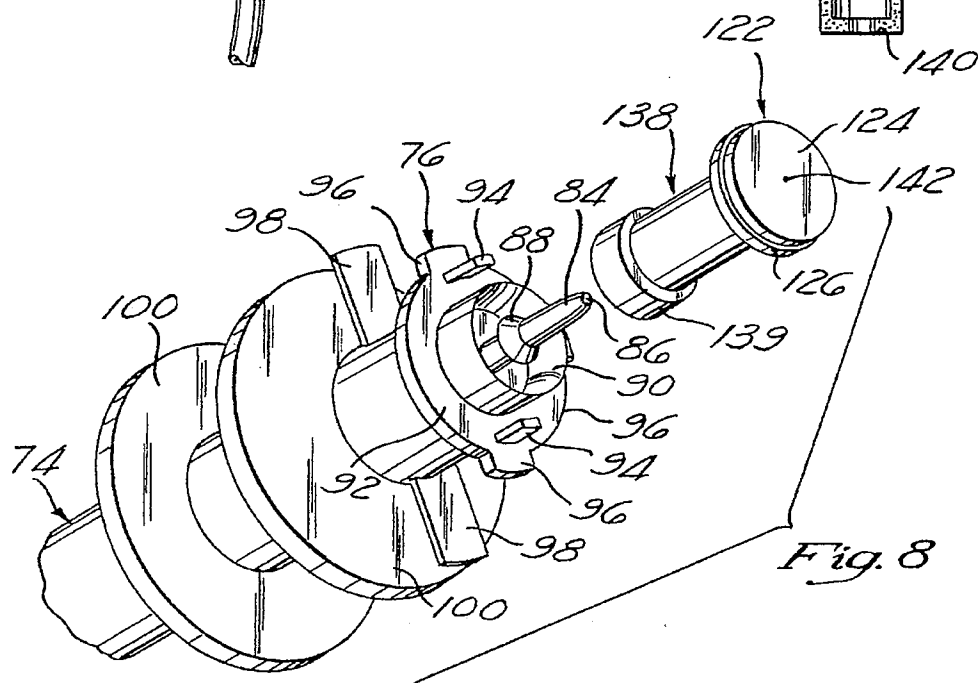
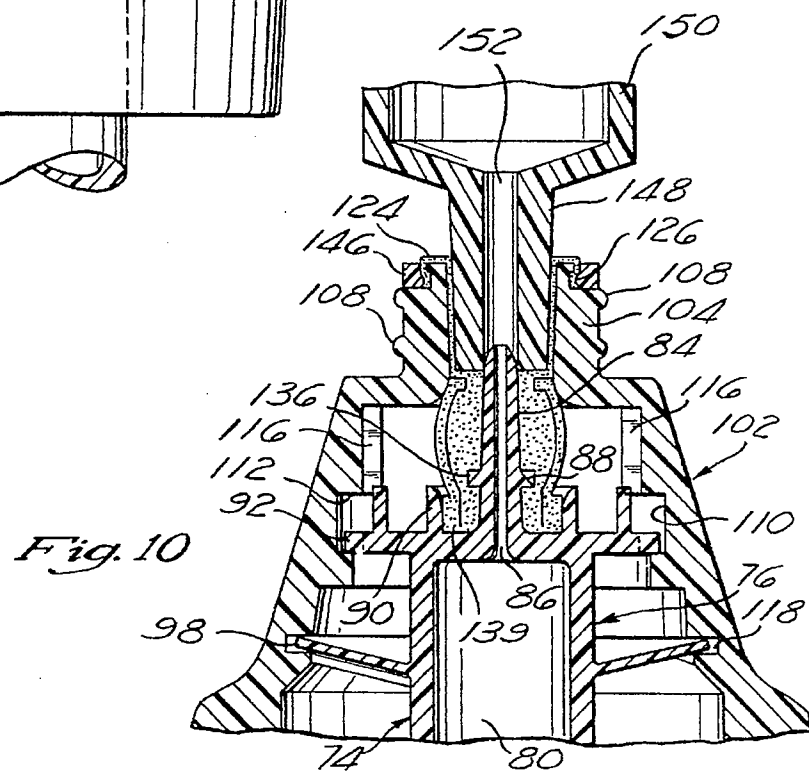
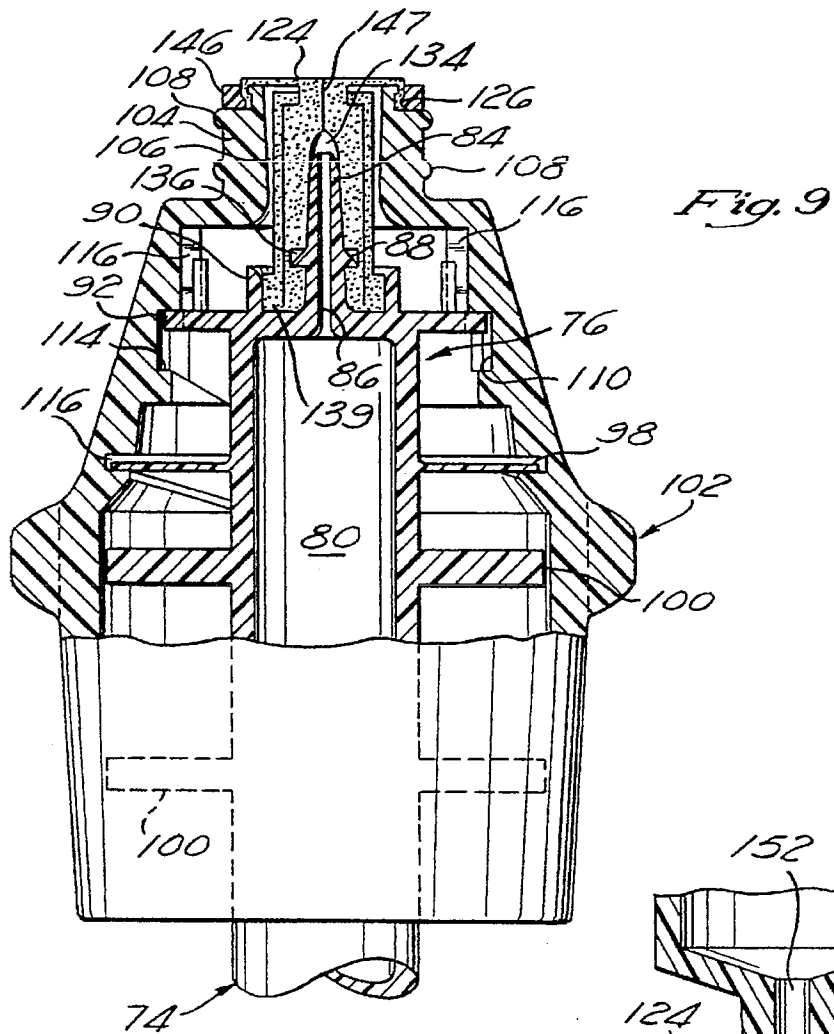


Fig. 8



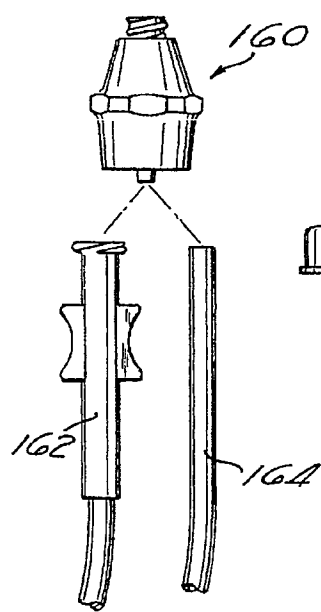


Fig. 11

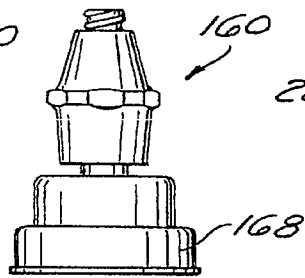


Fig. 12

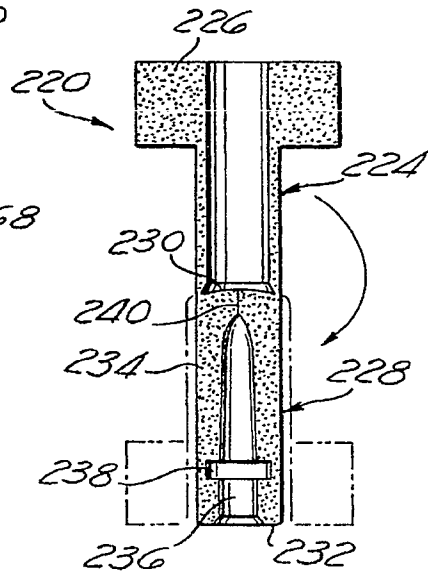


Fig. 13

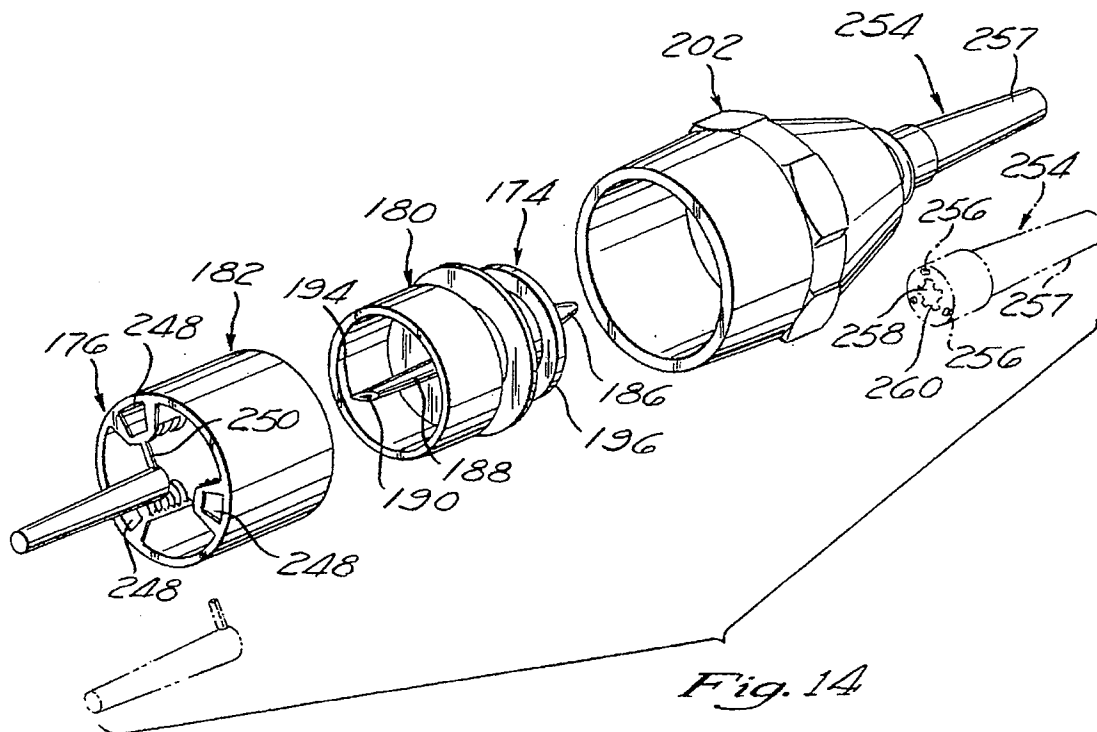


Fig. 14

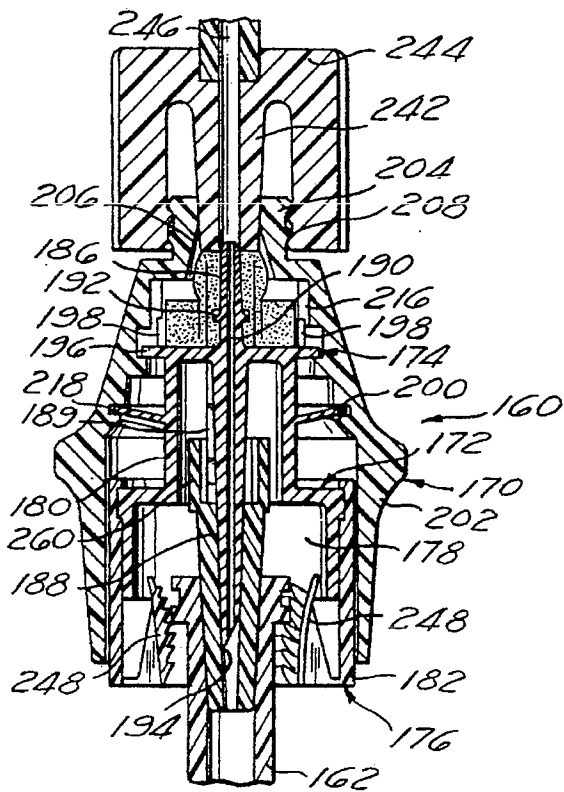


Fig. 15

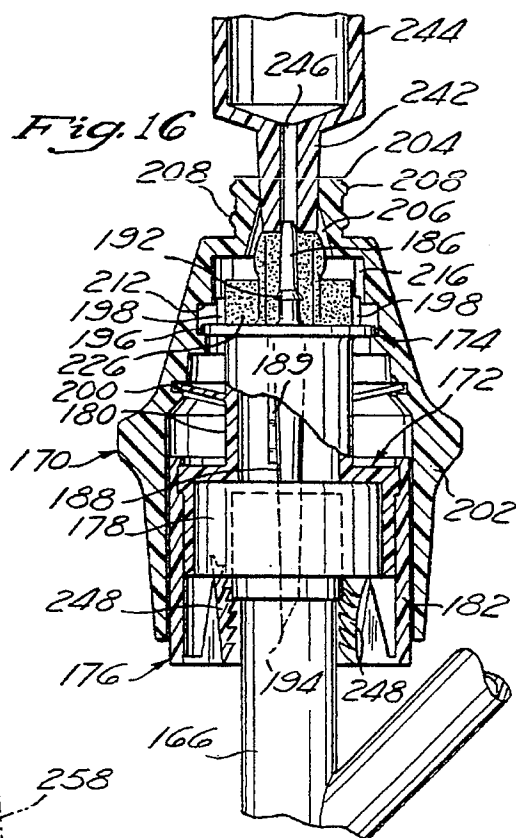


Fig. 16

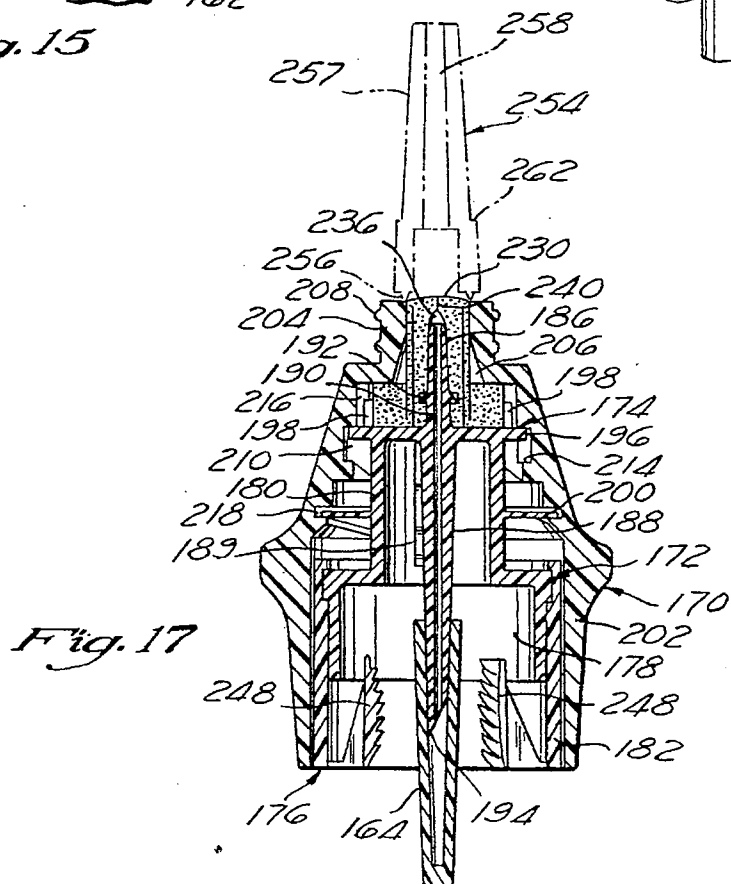


Fig. 17

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NEEDLELESS INJECTION SITE

FIELD OF THE INVENTION

The present invention relates generally to the medical arts, and more particularly to a needleless injection site for use in relation to intravenous infusions.

BACKGROUND OF THE INVENTION

It is common medical practice to intravenously infuse various fluids into the blood vessels of a patient. Such infusion is typically accomplished by the insertion of a hollow introducer needle into a target blood vessel. The introducer needle is fluidly connected to one end of an elongate, flexible tube, the opposite end of which is fluidly connected to a solution bag. The solution bag itself is typically suspended above the patient so as to allow the fluid to flow downwardly through the tubing and into the patient's blood vessel via the introducer needle which remains operatively positioned therewithin. The fluid tube and solution bag are connected to each other via a metering apparatus which controls the infusion rate of fluid from the bag into the tube.

In many intravenous infusion assemblies, an injection site is fluidly coupled within the tubing intermediate the introducer needle and the solution bag. The injection site typically has a Y-shaped configuration and comprises a tubular main body portion having a tubular side arm portion in fluid communication therewith. The distal end of the side arm portion is fluidly connected to the solution bag via an upper segment of the tubing, with the bottom end of the main body portion being fluidly connected to the introducer needle via a lower segment of the tubing. The top end of the main body portion is itself covered by a diaphragm which is typically fabricated from rubber or a similar resilient material.

The inclusion of the injection site within the tubing allows various medications to be selectively infused into the blood vessel of the patient by the addition thereof to the solution flowing from the solution bag into the blood vessel via the upper tubing segment, injection site, lower tubing segment and introducer needle. This supplemental infusion is typically accomplished through the utilization of a conventional syringe, the needle of which pierces and is extended through the diaphragm disposed on the top end of the main body portion of the injection site. Subsequent to the expulsion of the medication from within the syringe and into the flowing solution, the needle is retracted out of the main body portion of the injection site, with the aperture created in the diaphragm due to the passage of the needle therethrough being substantially closed upon such retraction due to the resiliency of the diaphragm. As will be recognized, the incorporation of the injection site within the tubing allows various medications to be intravenously administered to the patient through the existing infusion site within the blood vessel, thus eliminating the need to subject the patient to additional needle sticks.

Though providing certain benefits to the patient, the injection sites constructed in accordance with the prior art possess certain deficiencies which detract from their overall utility. As previously explained, the use of such injection sites typically requires that the needle of a conventional syringe be extended through (i.e., puncture) the diaphragm attached to the top end of the main body portion of the injection site. However, the necessity of having to utilize a syringe with a needle to facilitate the introduction of the medication into the solution flow is undesirable due to the

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risk of inadvertent needle sticks. In recognition of this deficiency, there has also been developed in the prior art needleless injection sites which incorporate a diaphragm adapted to assume open and closed configurations without having a needle inserted therein. Though these needleless injection sites eliminate the need of having to puncture the diaphragm with a needle, they also possess certain deficiencies which detract from their overall utility. Foremost of these deficiencies is the difficulty associated with disinfecting the injection site, and in particular the diaphragm thereof, subsequent to medication being infused therein. In this respect, after each use of the injection site the diaphragm must be cleaned, with such cleaning typically being accomplished through the application of alcohol or a similar disinfecting substance thereto. However, due to the configuration of the diaphragm, complete and effective disinfection thereof is often difficult to achieve, thus increasing the risk of the introduction of contaminants into the solution stream upon subsequent uses of the injection site. The present invention is adapted to overcome these and other deficiencies associated with prior art injection sites.

SUMMARY OF THE INVENTION

In accordance with a first embodiment of the present invention, there is provided a needleless injection site comprising a housing. The housing itself comprises a main body portion defining proximal and distal ends, and a bore extending axially therethrough. The housing further comprises a tubular side arm portion which is in fluid communication with the main body portion.

Attached to the proximal end of the main body portion is a reseal member which extends into the bore and includes an elastically openable and closable aperture formed therein. The reseal member normally resides in a closed position wherein the aperture is in a closed configuration. In the first embodiment, the reseal member is deformable such that the application of distally pressure thereto will cause it to distally advance within the bore to an open position wherein the aperture assumes an open configuration. Conversely, the removal of the distally directed pressure from the reseal member will cause it to resiliently return to the closed position wherein the aperture assumes the closed configuration.

The reseal member is preferably fabricated from silicone and comprises a circularly configured proximal portion which defines a top surface and has a flange formed about the periphery thereof for attaching the reseal member to the main body portion of the housing. The reseal member further comprises a cylindrically configured central portion which defines a side surface and a bottom surface having a conically shaped notch formed therein. The aperture extends from the top surface of the proximal portion to the apex of the notch. In addition to the proximal and central portions, the reseal member includes a tubular distal portion which is invertible and adapted to overlap the side surface of the central portion and apply a radially inward biasing force thereto when inverted which maintains the aperture in the closed configuration when no distally directed pressure is applied to the top surface of the proximal portion.

The injection site of the first embodiment further comprises a lock ring for securing the reseal member to the proximal end of the main body portion. In this respect, the flange of the reseal member is rigidly captured between the main body portion and the lock ring. Additionally, formed on the outer surface of the main body portion adjacent the

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proximal end thereof are Luer threads.

In accordance with a second embodiment of the present invention, there is provided a needleless injection site comprising a housing which also comprises a main body portion defining proximal and distal ends and a bore extending axially therethrough. Formed on the proximal end of the main body portion and extending axially therefrom is an elongate dilator projection. The dilator projection defines a longitudinally extending fluid passage which is in fluid communication with the bore. Attached to the proximal end of the main body portion is a connector cap which defines a central opening into which the dilator projection extends. The housing further comprises a tubular side arm portion which is in fluid communication with the main body portion.

Disposed within the opening of the connector cap is a reseal member which has an elastically openable and closable aperture formed therein, and normally resides in a closed position wherein the aperture is in a closed configuration. The dilator projection of the housing extends into the reseal member. The reseal member is deformable such that the application of distally directed pressure thereto will cause it to distally advance within the opening to an open position wherein the aperture is forced over a portion of the dilator projection. Conversely, the removal of the distally directed pressure from the reseal member will cause it to resiliently return to the closed position wherein the aperture assumes the closed configuration.

In the second embodiment, the reseal member is attached to the connector cap and comprises a circularly configured proximal portion which defines a top surface and has a flange formed about the periphery thereof for attaching the reseal member to the connector cap. The reseal member further comprises a cylindrically configured central portion which defines a side surface and a bottom surface having an elongate, generally concave recess formed therein which is sized and configured to receive the dilator projection. The aperture extends from the top surface of the proximal portion to the apex of the recess. In addition to the proximal and central portions, the reseal member includes a tubular distal portion which is invertible and adapted to overlap the side surface of the central portion and apply a radially inward biasing force thereto when inverted which maintains the aperture in the closed configuration when no distally directed pressure is applied to the top surface of the proximal portion. Like the reseal member previously described in relation to the first embodiment, the reseal member constructed in accordance with the second embodiment is preferably fabricated from silicone. Additionally, the reseal member is preferably cooperatively engaged to the dilator projection and disposed in abutting contact with the proximal end of the main body portion.

The connector cap of the housing includes Luer threads formed on the outer surface thereof adjacent the central opening. Additionally, the main body portion of the housing normally resides in a first position within the connector cap, and is adapted to move distally relative the connector cap to a second position therewithin when distally directed pressure is applied to the reseal member. The removal of the distally directed pressure from the reseal member causes the main body portion to resiliently return to the first position. The main body portion preferably includes a leaf spring molded thereon which is cooperatively engaged to the connector cap and adapted to bias the main body portion to the first position.

In accordance with a third embodiment of the present invention, there is provided a needleless injection site com-

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prising a housing. The housing itself comprises an adapter member defining proximal and distal ends, and an interior chamber. Formed on the proximal end of the adapter member is an elongate dilator projection which defines a proximal portion extending axially from the proximal end, a distal portion extending axially into the interior chamber, and a longitudinally extending fluid passage in fluid communication with the interior chamber. Attached to the adapter member is a connector cap which defines a central opening. The adapter member is disposed within the connector cap, with the proximal portion of the dilator projection extending into the opening thereof.

Disposed Within the opening is a reseal member which has an elastically openable and closeable aperture formed therein, and normally resides in the closed position wherein the aperture is in a closed configuration. The proximal portion of the dilator projection extends into the reseal member. The reseal member is deformable such that the application of distally directed pressure thereto will cause it to distally advance within the opening to an open position wherein the aperture is forced over the proximal portion of the dilator projection. Conversely, the removal of the distally directed pressure from the reseal member will cause it to resiliently return to the closed position wherein the aperture assumes the closed configuration. The reseal member, which is also preferably fabricated from silicone, comprises a tubular proximal portion and a cylindrically configured distal portion defining top, bottom and side surfaces, and including an elongate, generally concave recess formed in the bottom surface thereof which is sized and configured to receive the proximal portion of the dilator projection. The aperture extends from the top surface of the distal portion to the apex of the recess. The proximal portion is invertible and adapted to overlap the side surface of the distal portion and apply a radially inward biasing force thereto when inverted which maintains the aperture in the closed configuration when no distally directed pressure is applied to the top surface of the distal portion. The reseal member is preferably cooperatively engaged to the proximal portion of the dilator projection and disposed in abutting contact with the proximal end of the adapter member.

The connector cap of the housing constructed in accordance with the third embodiment also includes Luer threads formed on the outer surface thereof adjacent the central opening. Additionally, the adapter member normally resides in a first position within the connector cap, and is adapted to move distally relative the connector cap to a second position therewithin when distally directed pressure is applied to the reseal member. When the distally directed pressure is removed from the reseal member, the adapter member resiliently returns to the first position. The adapter member preferably includes a leaf spring molded thereon which is cooperatively engaged to the connector cap and adapted to bias the adapter member to the first position.

In the third embodiment, the distal portion of the dilator projection has a tapered outer surface for facilitating the connection of the adapter member and hence the housing to a tubular fluid line. In particular, the housing is connected to the fluid line via the insertion of the distal portion of the dilator projection into the lumen of the fluid line, with the distal portion being frictionally retained within the lumen subsequent to being inserted thereinto.

The adapter member further comprises a tubular adapter sleeve which is slidably extensible over and frictionally maintainable on the distal portion of the dilator projection for facilitating the connection of the housing to a Luer connector. The housing is connected to the Luer connector

via the insertion of the adapter sleeve into the lumen of the Luer connector. The distal portion of the dilator projection preferably has a tapered outer surface, with the adapter sleeve preferably having a tapered bore extending longitudinally therethrough which is complimentary to the outer surface of the distal portion of the dilator projection, thus facilitating the frictional retention of the adapter sleeve thereon. Additionally, the distal portion of the dilator projection preferably includes an elongate rib formed on the outer surface thereof, with the bore of the adapter sleeve defining an elongate slot therewithin which is sized and configured to receive the rib when the adapter sleeve is slidably advanced over the distal portion of the dilator projection. The receipt of the rib into the slot is operable to prevent the rotation of the adapter sleeve upon the distal portion of the dilator projection. Further, the adapter sleeve preferably has a tapered outer surface for frictionally retaining the adapter sleeve within the lumen of the Luer connector subsequent to being inserted thereinto.

The adapter member of the housing further defines a tubular lock region within the distal end thereof which is configured to engage the Luer threads of the Luer connector when the adapter sleeve is inserted into the lumen thereof. The lock region preferably defines a plurality of Luer thread pitch barbs therewithin which engage the Luer threads. The lock region of the adapter member is also used to facilitate the connection of the housing to a Y-injection site. In particular, the housing is connected to the Y-injection site via the insertion of the Y-injection site into the lock region of the adapter member, and the extension of the distal portion of the dilator projection thereinto. In the third embodiment, the adapter member preferably comprises an upper section defines the dilator projection, and a lower section which is rigidly attached to the upper section and defines the lock region, with the upper and lower sections defining the interior chamber when attached to each other.

Further in accordance with the present invention, there is provided a method of fabricating a reseal member for use in a needleless injection site. The method comprises the step of molding the reseal member to include a circularly configured proximal portion, a cylindrically configured central portion having an opening formed in the bottom surface thereof, an aperture extending from the top surface of the proximal portion to the opening, and a tubular distal portion. The method further comprises the step of inverting the distal portion in a manner causing it to overlap the side surface of the central portion and apply a radially inward biasing force thereto which maintains the aperture in a closed configuration. The method may further comprise the step of forming a flange about the periphery of the proximal portion. The opening formed within the central portion may comprise a conically-shaped notch, with the aperture extending from the top surface of the proximal portion to the apex of the notch. Alternatively, the opening may comprise an elongate, concave recess, with the aperture extending from the top surface of the proximal portion to the apex of the recess.

There is also provided a method of fabricating a reseal member for use in a needleless injection site which comprises the step of molding the reseal member to include a tubular proximal portion, a cylindrically configured distal portion having a concave recess formed in the bottom surface thereof, and an aperture extending from the top surface of the distal portion to the apex of the recess. The method further includes the step of inverting the proximal portion in a manner causing it to overlap the side surface of the distal portion and apply a radially inward biasing force thereto which maintains the aperture in a closed configura-

tion.

BRIEF DESCRIPTION OF THE DRAWINGS

These, as well as other features of the present invention, will become more apparent upon reference to the drawings wherein:

FIG. 1 is a perspective view of a needleless injection site constructed in accordance with a first embodiment of the present invention;

FIG. 2 is a cross-sectional view taken along line 2—2 of FIG. 1;

FIG. 2a is a cross sectional view of a modification of FIG. 2 incorporating an enlarged reseal flange and annular lock ring;

FIG. 3 is a cross-sectional view of the reseal member incorporated into the needleless site shown in FIG. 1;

FIG. 4 is a perspective view of the reseal member shown in FIG. 3;

FIG. 5 is a cross-sectional view illustrating the manner in which the reseal member is deformable from a closed to an open position;

FIG. 6 is a side elevational view of a needleless injection site constructed in accordance with a second embodiment of the present invention, and further illustrating various devices which may be connected thereto;

FIG. 7 is a cross-sectional view of the reseal member incorporated into the needleless injection site shown in FIG. 6;

FIG. 8 is an exploded perspective view of the main body portion and reseal member of the needleless injection site shown in FIG. 6;

FIG. 9 is a partial cross-sectional view of the needleless injection site shown in FIG. 6, with the reseal member thereof being in a closed position;

FIG. 10 is a partial cross-sectional view of the needleless injection site shown in FIG. 6, with the reseal member thereof being deformed into an open position;

FIG. 11 is a side elevational view of a needleless injection site constructed in accordance with a third embodiment of the present invention, and further illustrating a Luer connector and a tubing end to which it may be connected;

FIG. 12 is a side elevational view of the needleless injection site constructed in accordance with the third embodiment of the present invention as connected to a bottle;

FIG. 13 is a cross-sectional view of the reseal member incorporated into the needleless injection site shown in FIGS. 11 and 12;

FIG. 14 is an exploded perspective view of the needleless injection site constructed in accordance with the third embodiment of the present invention;

FIG. 15 is a cross-sectional view of the needleless injection site shown in FIGS. 11 and 12 as connected to a Luer connector, with the reseal member thereof being deformed into an open position;

FIG. 16 is a cross-sectional view of the needleless injection site shown in FIGS. 11 and 12 as connected to a Y-injection site, with the reseal member thereof being deformed into an open position; and

FIG. 17 is a cross-sectional view of the needleless injection site shown in FIGS. 11 and 12 as connected to a tubular fluid line, with the reseal member thereof being in a closed

position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings wherein the showings are for purposes of illustrating preferred embodiments of the present invention only, and not for purposes of limiting the same, FIG. 1 perspective illustrates a needleless injection site 10 constructed in accordance with a first embodiment of the present invention. In the first embodiment, the injection site 10 comprises a Y-shaped housing 12. The housing 12 itself comprises a main body portion 14 which defines a proximal end 16, a distal end 18 and a bore 20 extending axially therethrough. The housing 12 further comprises a tubular side arm 22 portion which extends angularly from the main body portion 14 and defines a bore 24 in fluid communication with the bore 20 of the main body portion 14. In typical intravenous infusion applications, the side arm portion 22 is fluidly connected to a suspended solution bag via an upper segment of tubular fluid line. The distal end 18 of the main body portion 14 is itself fluidly connected to a hollow introducer needle via an elongate lower segment of tubular fluid line, thus allowing the solution to flow from the bag into a target blood vessel via the upper tubing segment, injection site 10, lower tubing segment and introducer needle.

Referring now to FIGS. 2-5, attached to the proximal end 16 of the main body portion 14 is a reseal member 26 which is fabricated from a resilient material and extends into the bore 20. As best seen in FIGS. 3 and 4, the reseal member 26 comprises a circularly configured proximal portion 28 which defines a top surface 30 and includes a flange 32 formed about the periphery thereof. The reseal member 26 further comprises a cylindrically configured central portion 34 which defines a side surface 36 and a bottom surface 38 having a conically shaped notch 40 formed in the center thereof. In addition to the proximal and central portions 28, 34, the reseal member 26 comprises a tubular distal portion 42 which includes an annular lip 44 formed about the inner surface thereof. The distal portion 42 is preferably formed in a manner wherein a slit 46 is disposed in the corner region defined between the lip 44 and the remainder of the distal portion 42. Extending from the top surface 30 of the proximal portion 28 to the apex of the notch 40 is an aperture 48 which is elastically openable and closable. In the injection site 10, the reseal member 26 normally resides in a closed position wherein the aperture 48 is in a closed configuration.

To maintain the aperture 48 in the closed configuration, the distal portion 42 of the reseal member 26 is formed so as to be invertible in relation to the remainder thereof. As best seen in FIGS. 2 and 5, the distal portion 42, when inverted, is adapted to overlap the side surface 36 of the central portion 34 and apply a radially inward biasing force thereto which maintains the aperture in the closed configuration. Such inversion is accomplished by initially turning the lip 44 outwardly, thus causing the same to extend radially outward with respect to the remainder of the distal portion 42. The outward turning of the lip 44 is aided by the inclusion of the slit 46 within the distal portion 42. Thereafter, the distal portion 42 is rolled toward the proximal portion 28, with the lip 44 being inserted into the annular channel 50 defined between the proximal and central portions 28, 34. When the distal portion 42 is properly inverted, the reseal member 26 assumes the configuration shown in FIG. 2. For ease of manufacture, the reseal member 26 is

molded in the form shown in FIGS. 3 and 4, with the distal portion 42 thereof being inverted in the aforementioned manner prior to the attachment of the reseal member 26 to the proximal end 16 of the main body portion 14. As previously explained, due to the resiliency of the material from which the reseal member 26 is fabricated, the inversion of the distal portion 42 facilitates the application of a radially inward biasing force to the central portion 34, thus maintaining the aperture 48 in the closed configuration.

In the injection site 10, the housing 12 further comprises an annular lock ring 52 for securing the reseal member 26 to the proximal end 16 of the main body portion 14. In particular, the attachment of the reseal member 26 to the main body portion 14 is accomplished by the rigid capture of the flange 32 between the main body portion 14 and lock ring 52 which is itself attached to the main body portion 14 via a sonic bonding process. When attached to the main body portion 14 via the lock ring 52, the central portion 34 of the reseal member 26 (which is covered by the inverted distal portion 42) resides within the bore 20.

The reseal member 26, due to its construction, is deformable such that the application of distally directed pressure thereto will cause it to distally advance within the bore 20 to an open position wherein the aperture 48 assumes an open configuration (as shown in FIG. 5). Conversely, the removal of the distally directed pressure from the reseal member 26 will cause it to resiliently return to the closed position wherein the aperture 48 assumes the closed configuration. In particular, when the reseal member 26 is in the closed position (as shown in FIG. 2), the top surface 30 of the proximal portion 28 extends over (i.e., covers) the proximal end 16 of the main body portion 14, with the aperture 48 being in the closed configuration due to the radially inward biasing force applied to the central portion 34 by the inverted distal portion 42. When the tip 54 of an introducer device 56 is used to apply distally directed pressure to the top surface 30 of the proximal portion 28, such pressure application causes the reseal member 26 (with the exception of the flange 32) to distally advance within the bore 20 (as shown in FIG. 5). Due to the rigid attachment of the flange 32 to the proximal end 16 of the main body portion 14 via the lock ring 52, the advancement of the reseal member 26 distally within the bore 20 causes the aperture 48 to assume the open configuration, which allows fluid to flow from the outlet passage 58 of the introducer device 56 into the bore 20 via the pathway defined by the open aperture 48 and notch 40. Additionally, due to the resiliency of the reseal member 26, the removal of the introducer device 56 from within the injection site 10 allows it to resiliently return to its closed position (shown in FIG. 10), thus causing the aperture 48 to once again assume the closed configuration. In this respect, when no distally directed pressure is applied to the top surface 30 of the proximal portion 28, the aperture 48 is maintained in the closed configuration by the radially inward biasing force exerted on the central portion 34 by the inverted distal portion 42. The tip 54 of the introducer device 56 is preferably sized having an outer diameter dimension which is slightly less than the inner diameter dimension of the bore 20, thus allowing the stretched region of the proximal portion 28 to form a seal between the outer surface of the tip 54 and inner surface of the bore 20.

In the injection site 10, the reseal member 26 is preferably fabricated from silicone, though similar elastic materials such as rubber may be utilized as an alternative. Additionally, the outer surface of the main body portion 14 preferably includes Luer threads 60 formed thereon adjacent the proximal end 16 to allow introducer devices such as Luer con-

nectors to be interfaced to the injection site 10. Advantageously, the uniform top surface 30 defined by the proximal portion 28 when the reseal member 26 is in the closed position allows for the quick and easy cleaning and disinfection thereof. Though the reseal member 26 has been described as being used in conjunction with the Y-shaped housing 12, it will be recognized that the reseal member 26 may also be used in association with a Luer connector, a conventional tubular fluid line or any other type of injection site.

Referring now to FIG. 2a, there is depicted a reseal member 26a which is adapted to be attached to the proximal end of an alternative Y-shaped housing 12a. The reseal member 26a is substantially identical to the reseal member 26 previously described and comprises a circularly configured proximal portion 28a which defines a top surface 30a and includes the flange 32a formed about the periphery thereof. The reseal member 36a further comprises a cylindrically configured central portion 34a which defines a bottom surface 38a having a conically shaped notch 40a formed in the center thereof and a side surface which is overlapped by an inverted, tubular distal portion 42a. Extending from the top surface 30a of the proximal portion 28a to the apex of the notch 40a is an aperture 48a which is elastically openable and closable. The only distinction between the reseal member 26a and the reseal member 26 is in the configuration of the flange 32a which is substantially longer than the flange 32 for reasons which will be discussed below.

The housing 12a to which the reseal member 26a is attached is similar to the housing 12 previously described but does not include the Luer threads 60 formed on the outer surface on the main body portion 14a thereof. Rather, the proximal portion of the main body portion 14a of the housing 12a defines a generally smooth outer surface over which the flange 32a is extended. As an alternative to the lock ring 52 previously described, the housing 12a further comprises an annular lock ring 52a for securing the reseal member 26a to the proximal end of the main body portion 14a. In particular, the attachment of the reseal member 26a to the main body portion 14a is accomplished by the rigid capture of the flange 32a between the main body portion 14a and lock ring 52a which is itself attached to an annular shoulder 53a formed about the outer surface of the main body portion 14a via a sonic bonding process. The outer surface of the lock ring 52a preferably includes Luer threads 60a formed thereon to allow introducer devices such as Luer connectors to be interfaced to the housing 12a.

Though not shown, it will be recognized that alternative means may be utilized to apply a radially inward biasing force to the central portion 34, 34a of the reseal member 26, 26a to maintain the aperture 48, 48a in the closed configuration. In this respect, the reseal member 26, 26a may be formed without the invertible distal portion 42, 42a, with the radially inward biasing force being applied to the central portion 34, 34a by an O-ring which is received into the annular channel 50, 50a defined between the proximal portion 28, 28a and central portion 34, 34a.

Referring now to FIGS. 6-10, illustrated is a needleless injection site 70 constructed in accordance with a second embodiment of the present invention. In the second embodiment, the injection site 70 preferably comprises a Y-shaped housing 72, though the housing 72 may alternatively have a straight configuration. The housing 72 itself comprises a main body portion 74 which defines a proximal end 76, a distal end 78 and a bore 80 extending axially therethrough. Extending angularly from the main body portion 74 is a

tubular side arm portion 82 which is in fluid communication with the bore 80 of the main body portion 74. In typical intravenous infusion applications, the side arm portion 82 of the housing 72 is fluidly connected to a suspended solution bag via an upper segment of tubular fluid line. The distal end 78 of the main body portion 74 is itself fluidly connected to a hollow introducer needle via an elongate lower segment of tubular fluid line, thus allowing the solution to flow from the bag into a target blood vessel via the upper tubing segment, injection site 70, lower tubing segment and introducer needle.

Referring now to FIGS. 8-10, formed on and extending axially from the proximal end 76 of the main body portion 74 is an elongate dilator projection 84. The dilator projection 84 defines a longitudinally extending fluid passage 86 which is in fluid communication with the bore 80 and coaxially aligned therewith. Formed about the outer surface of the dilator projection 84 is a retaining lip 88 which has a generally triangular cross-sectional configuration. Also formed on the proximal end 76 of the main body portion 74 is an annular flange 90 which circumvents the dilator projection 84. As best seen in FIG. 7, the flange 90 is formed on the proximal end 76 in a manner wherein the dilator projection 84 is centrally positioned therewithin. Additionally, as best seen in FIGS. 9 and 10, the flange 90 is formed in a manner defining an arcuately contoured rim which terminates at approximately the distal-most surface of the retaining lip 88.

In addition to the dilator projection 84 and flange 90, formed on the proximal end 76 of the main body portion 74 and extending radially outward therefrom is a stop flange 92. Formed on the proximal surface of the stop flange 92 and extending perpendicularly relative thereto is an opposed pair of identically configured anti-rotation extensions 94. The extensions 94 each have a height substantially equal to that of the flange 90 and extend in generally parallel relation thereto. Extending radially from the peripheral edge of the stop flange 92 in opposed relation is a pair of identically configured stop tabs 96. Formed about and extending radially outward from the outer surface of the main body portion 74 in opposed relation is a pair of leaf springs 98. The leaf springs 98, which are positioned on the main body portion 74 distally from the stop flange 92, are thinly configured to provide the same with resiliency for reasons which will be discussed below. Also formed about and extending radially outward from the outer surface of the main body portion 74 in succession is a pair of identically configured centering flanges 100 which are positioned on the main body portion 74 distally from the leaf springs 98.

In the second embodiment, the housing 72 further comprises a hollow connector cap 102 which is attached to the proximal portion of the main body portion 74. The connector cap 102 includes an annular attachment region 104 formed on the proximal end thereof. The attachment region 104 defines a central opening 106 which communicates with the hollow interior of the connector cap 102. Additionally, formed on the outer surface of the attachment region 104 are Luer threads 108. The attachment of the connector cap 102 to the main body portion 74 is facilitated by the receipt of the stop tabs 96 into an annular channel 110 which is disposed within the inner surface of the connector cap 102 and defines a proximal stop surface 112 and a distal stop surface 114. When the stop tabs 96 are properly received into the channel 110, the extensions 94 formed on the proximal surface thereof are received into complimentary slots 116 which are disposed within the inner surface of the connector cap 102 and extend longitudinally from the proximal stop surface

112 of the channel 110 toward the proximal end of the connector cap 102. As will be discussed in more detail below, the receipt of the extensions 94 into the slots 116 is operable to prevent the rotation of the connector cap 102 relative the main body portion 74.

In addition to the receipt of the stop tabs 96 into the channel 110, the peripheral portions of the leaf springs 98 are received into an annular channel 118 which is also disposed in the inner surface of the connector cap 102 and positioned distally from the channel 110. When the stop tabs 96 and leaf springs 98 are received into the channels 110, 118, the dilator projection 84 extends axially into the central opening 106 of the connector cap 102, but does not protrude from the attachment region 104 thereof. When the connector cap 102 is attached to the main body portion 74 in the aforementioned manner, the centering flanges 100 are adapted to maintain the main body portion 74 centrally within the connector cap 102 such that the dilator projection 84, and in particular the fluid passage 86 thereof, remains coaxially positioned within the central opening 106.

Referring now to FIGS. 7-10, disposed within the central opening 106 of the connector cap 102 and cooperatively engaged to the dilator projection 84 is a reseal member 120 which is fabricated from a resilient material. As best seen in FIGS. 7 and 8, the reseal member 120 comprises a circularly configured proximal portion 122 which defines a top surface 124 and includes a flange 126 formed about the periphery thereof. The reseal member 120 further comprises a cylindrically configured central portion 128 which defines a side surface 130 and a bottom surface 132 having an elongate, generally concave recess 134 formed in the center thereof. Importantly, the recess 134 has a shape complimentary to that of the dilator projection 84 and defines an annular groove 136 within its side wall. In addition to the proximal and central portions 122, 128, the reseal member 120 comprises a tubular distal portion 138 which includes an annular lip 140 formed about the inner surface thereof. Also formed about the inner surface of the distal portion 138 immediately adjacent the bottom surface 132 of the central portion 128 is an annular extension 141. Extending from the top surface 124 of the proximal portion 122 to the apex of the recess 134 is an aperture 142 which is elastically openable and closable. In the injection site 70, the reseal member 120 normally resides in a closed position wherein the aperture 142 is in a closed configuration.

To maintain the aperture 142 in the closed configuration, the distal portion 138 of the reseal member 120 is formed so as to be invertible in relation to the remainder thereof. As best seen in FIG. 7, the distal portion 138, when inverted, is adapted to overlap the side surface 130 of the central portion 128 and apply a radially inward biasing force thereto which maintains the aperture 142 in the closed configuration. Such inversion is accomplished by initially turning the lip 140 outwardly, thus causing the same to extend radially outward with respect to the remainder of the distal portion 138. Thereafter, the distal portion 138 is rolled toward the proximal portion 122, with the lip 140 being inserted into the annular channel 144 defined between the proximal and central portions 122, 128. When the lip 140 is inserted into the channel 144, the extension 141 extends radially outward with respect to the remainder of the reseal member 120. When the distal portion 138 is properly inverted, the reseal member assumes the configuration shown in FIG. 8. For ease of manufacture, the reseal member 120 is molded in the form shown in FIG. 7, with the distal portion 138 thereof being inverted in the aforementioned manner prior to the insertion of the reseal member 120 into the central opening

106 and engagement thereof to the dilator projection 84. As previously explained, due to the resiliency of the material from which the reseal member 120 is fabricated, the inversion of the distal portion 138 facilitates the application of a radially inward biasing force to the central portion 128, thus maintaining the aperture 142 in the closed configuration.

In the injection site 70, the housing 72 further comprises an annular lock ring 146 for securing the reseal member 120 to the connector cap 102, and in particular to the attachment region 104 thereof. The attachment of the reseal member 120 to the connector cap 102 is accomplished by the rigid capture of the flange 126 between the outer surface of the attachment region 104 and lock ring 146 which is itself attached to the connector cap 102 via a sonic bonding process. When attached to the connector cap 102 via the lock ring 146, the central portion 128 of the reseal member 120 (which is covered by the inverted distal portion 138) resides within the central opening 106 and hollow interior of the connector cap 102.

As previously indicated, in addition to being rigidly secured to the connector cap 102, the reseal member 120 is cooperatively engaged to the dilator projection 84. In the injection site 70, such cooperative engagement is achieved by the insertion of the dilator projection 84 into the recess 134 of the reseal member 120. When the dilator projection 84 is fully inserted into the recess 134, the retaining lip 88 formed thereabout is received into the groove 136 disposed within the side wall of the recess 134. When the retaining lip 88 is received into the groove 136, the distal portion of the reseal member 120 is compressed into and thus tightly contained within the annular space defined between the dilator projection 84 and the flange 90, with the extension 141 extending radially outward from the reseal member 120 being abutted against the inner surface of the flange 90 and the distal end of the reseal member 120 being disposed in abutting contact with the proximal end 76 of the main body portion 74. Advantageously, the formation of the proximal rim of the flange 90 with an arcuate contour aids in the insertion of the distal portion of the reseal member 120 into the annular space between the dilator projection 84 and flange 90. The distal portion of the reseal member 120 is maintained in the annular space between the dilator projection 84 and the flange 90 in part by the retaining lip 88 which, when received into the groove 136, prevents the movement of the reseal member 120 proximally relative to the dilator projection 84. As will be recognized, the engagement of the reseal member 120 to the dilator projection 84 typically occurs prior to the attachment thereof to the connector cap 102 via the lock ring 146.

The reseal member 120, due to its construction, is deformable such that the application of distally directed pressure thereto will cause it to distally advance within the central opening 106 to an open position wherein the aperture 142 assumes an open configuration (as shown in FIG. 10). Conversely, the removal of the distally directed pressure from the reseal member 120 will cause it to resiliently return to the closed position wherein the aperture 142 assumes the closed configuration (as shown in FIG. 9). In particular, when the reseal member 120 is in the closed position, the top surface 124 of the proximal portion 122 extends over (i.e., covers) the proximal end of the attachment region 104, with the aperture 142 being in the closed configuration due to the radially inward biasing force applied to the central portion 128 by the inverted distal portion 138. When the tip 148 of an introducer device 150 (such as a syringe or Luer connector as shown in FIG. 6) is used to apply distally directed pressure to the top surface 124 of the proximal portion 122,

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such pressure application causes the reseal member 120 (with the exception of the flange 126) to distally advance within the central opening 106, as shown in FIG. 10.

The advancement of the reseal member 120 distally within the central opening 106 causes the aperture 142 to be forced over the dilator projection 84 in a manner wherein the proximal tip of the dilator projection 84 protrudes from the top surface 124 of the proximal portion 122 and is received into the outlet passage 152 of the introducer device 150. The extension of the dilator projection 84 through the aperture 142 allows fluid to flow from the outlet passage 152 of the introducer device 150 into the bore 80 via the fluid passage 86 of the dilator projection 84. Due to the resiliency of the reseal member 120, its engagement to the dilator projection 84, and its rigid attachment to the attachment region 104, the removal of the introducer device 150 from within the injection site 70 allows it to resiliently return to its closed position, thus causing the aperture 142 to once again assume the closed configuration. In this respect, when no distally directed pressure is applied to the top surface 124 of the proximal portion 122, the aperture 142 is maintained in the closed configuration by the radially inward biasing force exerted on the central portion 128 by the inverted distal portion 138. The tip 148 of the introducer device 150 is preferably sized having an outer diameter dimension which is slightly less than the inner diameter dimension of the central opening 106, thus allowing the stretched region of the proximal portion 122 to form a seal between the outer surface of the tip 148 and the inner surface of the central opening 106.

In the injection site 70, the reseal member 120 is preferably fabricated from silicone, though similar elastic materials such as rubber may be utilized as an alternative. Advantageously, the Luer threads 108 formed on the outer surface of the attachment region 104 allow introducer devices such as Luer connectors to be interfaced to the injection site 70. Additionally, the uniform top surface 124 defined by the proximal portion 122 when the reseal member 120 is in the closed position allows for the quick and easy cleaning and disinfection thereof.

Referring now to FIGS. 9 and 10, the main body portion 74 of the housing 72 normally resides in a first position within the connector cap 102 (as shown in FIG. 9), and is adapted to move distally relative the connector cap 102 to a second position therewithin when distally directed pressure is applied to the reseal member 120 (as shown in FIG. 10). When the distally directed pressure is removed from the reseal member 120, the main body portion 74 is adapted to resiliently return to the first position. In the injection site 70, the main body portion 74 is biased to the first position by the leaf springs 98 which are molded on the outer surface thereof and received into the channel 118 disposed in the inner surface of the connector cap 102. When distally directed pressure is applied to the reseal member 120, and in particular the top surface 124 of the proximal portion 122, the main body portion 74 is moved distally within the interior of the connector cap 102 toward its second position, thus resulting in the flexion of the leaf springs 98. The distal movement of the main body portion 74 within the connector cap 102 is limited by the abutment of the stop tabs 96 against the distal stop surface 114 defined by the channel 110. When such abutment occurs, the main body portion 74 resides in the second position. Importantly, the anti-rotation extensions 94 are sized such that when the stop tabs 96 are abutted against the distal stop surface 114, portions of the extensions 94 remain within their respective slots 116. The distally directed pressure exerted on the top surface 124 of the

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proximal portion 122 is transmitted to the main body portion 74 via the reseal member 120 which, as previously indicated, is cooperatively engaged to the dilator projection 84 and abutted against the proximal end 76 of the main body portion 74.

When the distally directed pressure is removed from the top surface 124 of the proximal portion 122, the leaf springs 98 returns to their original, unflexed positions which results in the movement of the main body portion 74 proximally within the connector cap 102 toward its first position. The proximal movement of the main body portion 74 within the connector cap 102 is limited by the abutment of the stop tabs 96 against the proximal stop surface 112 defined by the channel 110. When such abutment occurs, the main body portion 74 resides in the first position. Importantly, the length of travel of the main body portion 74 when it moves from the first to the second positions is significantly less than the length of travel of the reseal member 120 when it moves from the closed position to the open position, thus allowing the aperture 142 of the reseal member 120 to be forced over the dilator projection 84 despite the distal movement of the main body portion 74 within the connector cap 102. The return of the main body portion 74 to the first position, though primarily being facilitated by the action of the leaf springs 98, is also aided by the reseal member 120. In this respect, due to the cooperative engagement of the reseal member 120 to the dilator projection 84 as facilitated by the receipt of the retaining lip 88 into the groove 136, the resilient return of the reseal member 120 to the closed position pulls the dilator projection 84, and hence the main body portion 74, proximally toward the proximal end of the connector cap 102.

Though not shown, it will be recognized that alternative means may be employed to provide the radially inwardly biasing force to the central portion 128 of the reseal member 120 to maintain the aperture 142 in the closed configuration. In this respect, the reseal member 120 may be formed without the invertable, tubular distal portion 138, with the radially inwardly biasing force being applied to the central portion 128 via an O-ring which is received into the annular channel 144 defined between the proximal and central portions 122, 128.

Referring now to FIGS. 11-17, illustrated is a needleless injection site 160 constructed in accordance with a third embodiment of the present invention. As will be described in more detail below, the injection site 160 is adapted to be selectively coupled to a Luer connector 162 (as shown in FIGS. 11 and 15), a standard tubular fluid line 164 (as shown in FIGS. 11 and 17), a Y-injection site (as shown in FIG. 16), and a bottle 168 (as shown in FIG. 12). However, it will be recognized that the injection site 160 may additionally be fluidly coupled to various other intravenous infusion components. The injection site 160 comprises a housing 170 which itself comprises an adapter member 172 defining a proximal end 174, a distal end 176 and an interior chamber 178.

Referring now to FIGS. 14-17, the adapter member 172 comprises an upper section 180 which defines the proximal end 174, and a lower section 182 which is rigidly attached to the upper section 180 and defines the distal end 176. The upper and lower sections 180, 182, when attached to each other, define the interior chamber 178. When the upper and lower sections 180, 182 are rigidly attached to each other, the distal portion of the upper section 180 is concentrically positioned within the proximal portion of the lower section 182. Formed on the proximal end 174 of the adapter member 172 is an elongate dilator projection 184 which defines a

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proximal portion 186 extending axially from the proximal end 174, and a distal portion 188 extending axially into the interior chamber 178. The dilator projection 184 further defines a longitudinally extending fluid passage 190 which is in fluid communication with the interior chamber 178. Formed about the outer surface of the proximal portion 186 of the dilator projection 184 is a retaining lip 192 which has a generally triangular cross-sectional configuration. The distal portion 188 of the dilator projection 184 preferably has a tapered outer surface for facilitating the connection of the housing 170 to the fluid line 164, as will be described in more detail below. Additionally, the distal end of the distal portion 188 preferably has a beveled configuration defining a piercing tip 194. Formed on the tapered outer surface of the distal portion 188 and extending longitudinally from the proximal end 174 of the adapter member 172 to approximately the halfway point of the distal portion 188 is an elongate rib 189, the use of which will also be discussed below.

In addition to the dilator projection 184, formed on the proximal end 174 of the adapter member 172 and extending radially outward therefrom is a stop flange 196. Formed on the proximal surface of the stop flange 196 and extending perpendicularly relative thereto is an opposed pair of identically configured anti-rotation extensions 198. Additionally, formed about and extending radially outward from the outer surface of the adapter member 172, and in particular the upper section 180 thereof, is a leaf spring 200. The leaf spring 200, which is positioned on the upper section 180 distally from the stop flange 196, is thinly configured to provide the same with resiliency for reasons which will also be discussed below.

In the third embodiment, the housing 170 further comprises a hollow connector cap 202 which is attached to the adapter member 172. The connector cap 202 includes an annular attachment region 204 formed on the proximal end thereof. The attachment region 204 defines a central opening 206 which communicates with the hollow interior of the connector cap 202. Additionally, formed on the outer surface of the attachment region 204 are Luer threads 208. The attachment of the connector cap 202 to the adapter member 172 is facilitated by the receipt of the peripheral portion of the stop flange 196 into an annular channel 210 which is disposed within the inner surface of the connector cap 202 and defines a proximal stop surface 212 and a distal stop surface 214. When the stop flange 196 is properly received into the channel 210, the extensions 198 formed on the proximal surface thereof are received into complimentary slots 216 which are disposed within the inner surface of the connector cap 202 and extend longitudinally from the proximal stop surface 212 of the channel 210 toward the proximal end of the connector cap 202. As will be discussed in more detail below, the receipt of the extensions 198 into the slots 216 is operable to prevent the rotation of the connector cap 202 relative to the adapter member 172.

In addition to the receipt of the stop flange 196 into the channel 210, the peripheral portion of the leaf spring 200 is received into an annular channel 218 which is also disposed in the inner surface of the connector cap 202 and positioned distally from the channel 210. When then stop flange 196 and leaf spring 200 are received into the channels 210, 218, the proximal portion 186 of the dilator projection 184 extends axially into the central opening 206 of the connector cap 202, but does not protrude from the attachment region 204 thereof. The lower section 182 of the adapter member 72 is preferably sized having an outer diameter dimension slightly less than the inner diameter dimension of the

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connector cap 202 for purposes of maintaining the adapter member 172 centrally within the connector cap 202 such that the proximal portion 186 of the dilator projection 184, and in particular the fluid passage 190 thereof, remains coaxially positioned within the central opening 206.

Referring now to FIGS. 13 and 17, disposed within the central opening 206 of the connector cap 202 and cooperatively engaged to the proximal portion 186 of the dilator projection 184 is a reseal member 220 which is fabricated from a resilient material. The reseal member 220 comprises a tubular proximal portion 224 having an extension 226 formed about the outer surface thereof. The reseal member 220 further comprises a cylindrically configured distal portion 228 which defines a top surface 230, bottom surface 232 and side surface 234. Formed in the center of the bottom surface 232 is an elongate, generally concave recess 236 which has a shape complimentary to that of the proximal portion 186 of the dilator projection 184 and defines an annular groove 238 within its side wall. Extending from the top surface 230 of the distal portion 228 to the apex of the recess 236 is an aperture 240 which is elastically openable and closable. In the injection site 160, the reseal member 220 normally resides in a closed position wherein the aperture 240 is in a closed configuration.

To maintain the aperture 240 in the closed configuration, the proximal portion 224 of the reseal member 220 is formed so as to be invertible in relation to the remainder thereof. As best seen in FIG. 13, the proximal portion 224, when inverted, is adapted to overlap the side surface 234 of the distal portion 228 and apply a radially inward biasing force thereto which maintains the aperture 240 in the closed configuration. Such inversion is accomplished by initially rolling the proximal portion 224 toward the distal portion 228, and thereafter turning the extension 226 outwardly so as to cause the same to extend radially outward with respect to the remainder of the reseal member 220. When the proximal portion 224 is properly inverted, the reseal member assumes the configuration shown in FIG. 17. For ease of manufacture, the reseal member 220 is molded in the form shown in FIG. 13, with the proximal portion 224 thereof being inverted in the aforementioned manner prior to the insertion of the reseal member 220 into the central opening 206 and the engagement thereof to the proximal portion 186 of the dilator projection 184. As previously explained, due to the resiliency of the material from which the reseal member 220 is fabricated, the inversion of the proximal portion 224 facilitates the application of a radially inward biasing force to the distal portion 228, thus maintaining the aperture 240 in the closed configuration. When the reseal member 220 is fully inserted into the central opening 206 and cooperatively engaged to the proximal portion 186 of the dilator projection 184, the distal portion 228 of the reseal member 220 (which is covered by the inverted proximal portion 224) resides within the central opening 206 and hollow interior of the connector cap 202. Additionally, the top surface 230 of the reseal member 220, which has a slight arcuate contour, is substantially flush with the proximal end of the attachment region 204.

As previously indicated, the reseal member 220 is cooperatively engaged to the proximal portion 186 of the dilator projection 184. In the injection site 160, such cooperative engagement is achieved by the insertion of the proximal portion 186 into the recess 236 of the reseal member 220. When the proximal portion 186 is fully inserted into the recess 236, the retaining lip 192 formed thereabout is received into the groove 238 disposed within the side wall of the recess 236. When the retaining lip 192 is received into

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the groove 238, the distal portion of the reseal member 220 is forced between the proximal portion 186 and the extensions 198, with the extension 226 extending radially outward from the reseal member 220 being abutted against the inner surfaces of the extensions 198 and the distal end of the reseal member 220 being disposed in abutting contact with the proximal end 174 of the adapter member 172. The reseal member 220 is tightly held by the proximal portion 186 of the dilator projection 184 and extensions 198 when forced therebetween in the aforementioned manner. The distal portion of the reseal member 220 is maintained between the proximal portion 186 and the extensions 198 in part by the retaining lip 192 which, when received into the groove 238, prevents the movement of the reseal member 220 proximally relative to the proximal portion 186.

The reseal member 220, due to its construction, is deformable such that the application of distally directed pressure thereto will cause it to distally advance within the central opening 206 to an open position wherein the aperture 240 assumes an open configuration (as shown in FIGS. 15 and 16). Conversely, the removal of the distally directed pressure from the reseal member 220 will cause it to resiliently return to the closed position wherein the aperture 240 assumes the closed configuration (as shown in FIG. 17). When the reseal member 220 is in the closed position, the top surface 230 thereof is substantially flush with the proximal end of the attachment region 204, with the aperture 240 being in the closed configuration due to the radially inward biasing force applied to the distal portion 228 by the inverted proximal portion 224. When the tip 242 of an introducer device 244 (such as a Luer connector as shown in FIG. 15 and a syringe as shown in FIG. 16) is used to apply distally directed pressure to the top surface 230, such pressure application causes the reseal member 220 to distally advance within the central opening 206, as shown in FIGS. 5 and 16.

The advancement of the reseal member 220 distally within the central opening 206 causes the aperture 240 to be forced over the proximal portion 186 of the dilator projection 184 in a manner wherein the proximal tip of the proximal portion 186 protrudes from the top surface 230 of the distal portion 228 and is received into the outlet passage 246 of the introducer device 244. The extension of the proximal portion 186 through the aperture 240 allows fluid to flow from the outlet passage 246 of the introducer device 244 into and through the fluid passage 190 of the dilator projection 184. Due to the resiliency of the reseal member 220 and its engagement to the dilator projection 184, the removal of the introducer device 244 from within the injection site 160 allows it to resiliently return to its closed position, thus causing the aperture 240 to once again assume the closed configuration. In this respect, when no distally directed pressure is applied to the top surface 230 of the distal portion 238, the aperture 240 is maintained in the closed configuration by the radially inward biasing force exerted on the distal portion 238 by the inverted proximal portion 224.

In the injection site 160, the reseal member 220 is preferably fabricated from silicone, though similar elastic materials such as rubber may be utilized as an alternative. The Luer threads 208 formed on the outer surface of the attachment region 204 allow an introducer device 244 such as the Luer connector shown in FIG. 15 to be maintained in coupled engagement to the injection site 160. Additionally, the uniform top surface 230 defined by the distal portion 228 when the reseal member 220 is in the closed position allows for the quick and easy cleaning and disinfection thereof.

Referring now to FIGS. 15-17, the adapter member 172

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of the housing 170 normally resides in a first position within the connector cap 202 (as shown in FIG. 17), and is adapted to move distally relative to the connector cap 202 to a second position therewithin when distally directed pressure is applied to the reseal member 220 (as shown in FIGS. 15 and 16). When the distally directed pressure is removed from the reseal member 220, the adapter member 172 is adapted to resiliently return to the first position. In the injection site 160, the adapter member 172 is biased to the first position by the leaf spring 200 which is molded on the outer surface of the upper section 180 thereof and received into the channel 210 disposed in the inner surface of the connector cap 202. When distally directed pressure is applied to the reseal member 220, and in particular the top surface 230 of the distal portion 228, the adapter member 172 is moved distally within the interior of the connector cap 202 toward its second position, thus resulting in the flexion of the leaf spring 200. The distal movement of the adapter member 172 within the connector cap 202 is limited by the abutment of the peripheral portion of the stop flange 196 against the distal stop surface 214 defined by the channel 210. When such abutment occurs, the adapter member 172 resides in the second position. Importantly, the anti-rotation extensions 198 are sized such that when the stop flange is abutted against the distal stop surface 214, portions of the extensions 198 remain within their respective slots 216. The distally directed pressure exerted on the top surface 230 of the distal portion 228 is transmitted to the adapter member 172 via the reseal member 220 which, as previously indicated, is cooperatively engaged to the proximal portion 186 of the dilator projection 184 and abutted against the proximal end 174 of the adapter member 172.

When the distally directed pressure is removed from the top surface 230 of the distal portion 228, the leaf spring 200 returns to its original, unflexed position which results in the movement of the adapter member 172 proximally within the connector cap 202 toward its first position. The proximal movement of the adapter member 172 within the connector cap 202 is limited by the abutment of the peripheral portion of the stop flange 196 against the proximal stop surface 212 defined by the channel 210. When such abutment occurs, the adapter member 172 resides in the first position. Importantly, the length of travel of the adapter member 172 when it moves from the first to the second positions is significantly less than the length of travel of the reseal member 220 when it moves from the closed position to the open position, thus allowing the aperture 240 of the reseal member 220 to be forced over the proximal portion 186 of the dilator projection 184 despite the distal movement of the adapter member 172 within the connector cap 202. Additionally, the anti-rotation extensions 198 are positioned on the proximal surface of the stop flange 196 so as to be longitudinally movable within the slots 216 yet prevent the extension 226 of the reseal member 220 which is abutted against the inner surfaces thereof from contacting the inner surface of the connector cap 202. The return of the adapter member 172 to the first position, though primarily being facilitated by the action of the leaf spring 200, is also aided by the reseal member 220. In this respect, due to the cooperative engagement of the reseal member 220 to the proximal portion 186 of the dilator projection 184 as facilitated by the receipt of the retaining lip 192 into the groove 238, the resilient return of the reseal member 220 to the closed position pulls the dilator projection 184, and hence the adapter member 172, proximally toward the proximal end of the connector cap 202.

Referring now to FIGS. 14 and 17, defined within the

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distal end 176 of the adapter member 172, and in particular the lower section 182 thereof, is a lock region for facilitating the connection of the injection site 160 to an infusion component such as the Luer connector 162, Y-injection site 166 and bottle 168. The lock region of the adapter member 172 preferably comprises three sets of Luer thread pitch barbs 248 which are formed on the inner surface of the lower section 182 in equidistantly spaced intervals of approximately 120°. Each set of pitch barbs 248 extends longitudinally from the distal end 176 of the adapter member 172 into the interior chamber 178, and terminates at approximately the distal end of the upper section 180. As best seen in FIG. 17, each set of pitch barbs 248 is formed within the lower section 182 so as to be oriented radially inward from the inner surface thereof.

As previously explained, the adapter member 172 of the housing 170 is comprised of the upper and lower sections 180, 182 which are rigidly attached to each other. In the third embodiment, the lower section 182 of the adapter member 172 is molded to include a cover member 250 which is attached to one of the sets of pitch barbs 248 via a tang 252. The cover member 250 defines a tapered bore which is complimentary to the tapered outer surface of the distal portion 188 of the dilator projection 184. In this respect, subsequent to the assembly of the injection site 160 in the aforementioned manner, the tang 252 is manually broken, thus allowing the cover member 250 to be slidably advanced over the distal portion 188 of the dilator projection 184. Due to the bore of the cover member 250 and the distal portion 188 having mutually tapered configurations, the cover member 250 is frictionally maintained upon the distal portion 188 subsequent to being slidably advanced over the same. Advantageously, the cover member 250 prevents any inadvertent contamination of the distal portion 188 prior to the incorporation of the injection site 160 into an intravenous infusion assembly. The cover member 250 also prevents a user from being inadvertently injured by the piercing tip 194 of the distal portion 188.

In addition to the lower section 182 being molded with the cover member 250, the connector cap 202 of the injection site 160 is molded to include a tubular adapter sleeve 254 which is attached to the proximal end of the attachment region 204 via three (3) equidistantly spaced tangs 256. The adapter sleeve 254 has a tapered outer surface 257 and includes a tapered bore 258 extending longitudinally there-through which, like the bore of the cover member 250, is complimentary to the tapered outer surface of the distal portion 188 of the dilator projection 184. Disposed within the side wall of the bore 258 are a plurality of equidistantly spaced slots 260 which extend longitudinally from the end of the adapter sleeve 254 of greater diameter to a depth approximately commensurate with a shoulder 262 defined within the outer surface 257. As will be discussed in more detail below, the adapter sleeve 254 is used to facilitate the attachment of the injection site 160 to the Luer connector 162. As will be recognized, the cover member 250 is necessarily removed from the lower section 182 (or from upon the distal portion 188) and the adapter sleeve 254 removed from the connector cap 202 prior to the utilization of the injection site 160.

As previously indicated, the injection site 160 is adapted to be engaged to the Luer connector 162, fluid line 164, Y-injection site 166 and bottle 168. As seen in FIG. 15, the engagement of the injection site 160 to the Luer connector 162 is accomplished by slidably advancing the adapter sleeve 254 over the distal portion 188 of the dilator projection 184 subsequent to the removal of the cover member 250

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therefrom and the detachment of the adapter sleeve 254 from the connector cap 202. Since the outer surface of the distal portion 188 and the bore 258 of the adapter sleeve 254 have mutually tapered configurations, the adapter sleeve 254 is frictionally maintained upon the distal portion 188 subsequent to being slidably advanced over the same. Importantly, each of the slots 260 is sized and configured to slidably receive the rib 189 formed on the outer surface of the distal portion 188, with the advancement of the adapter sleeve 254 proximally along the distal portion 188 being limited by the abutment of the distal end of the rib 189 against the closed end of the slot 260 into which it is received. Advantageously, the receipt of the rib 189 into the slot 260 is operable to prevent the rotation of the adapter sleeve 254 upon the distal portion 188 of the dilator projection 184.

Subsequent to the attachment of the adapter sleeve 254 to the distal portion 188 in the aforementioned manner, the adapter sleeve 254 is slidably inserted into the lumen of the Luer connector 162. The advancement of the adapter sleeve 254 into the lumen of the Luer connector 162 is continued until such time as the Luer threads formed on the outer surface of the Luer connector 162 are engaged by the pitch barbs 248 of the lock region. Due to the tapered outer surface 257 of the adapter sleeve 254, the same is frictionally maintained within the lumen of the Luer connector 162 subsequent to being inserted thereinto. Additionally, the Luer connector 162 is prevented from being pulled distally away from the adapter member 172, and in particular the adapter sleeve 254, by the engagement of the pitch barbs 248 to the Luer threads thereof. As such, the combination of the frictional retention of the adapter sleeve 254 within the lumen and the engagement of the pitch barbs 248 to the Luer threads creates a secure interface between the injection site 160 and the Luer connector 162. When the reseal member 220 is moved to the open position, fluid flows from the outlet passage 246 of the introducer device 244 into the lumen of the Luer connector 162 via the fluid passage 190 of the dilator projection 184 and bore 258 of the adapter sleeve 254.

Referring now to FIG. 16, the engagement of the injection site 160 to the Y-injection site 166 is accomplished by initially removing the cover member 250 from the distal portion 188 of the dilator projection 184, and removing the adapter sleeve 254 from the connector cap 202. Thereafter, the injection site 160, and in particular the adapter member 172 thereof, is advanced over the top end of the Y-injection site 166 in a manner wherein the distal portion 188 of the dilator projection 184 is extended into the Y-injection site 166 (with any diaphragm attached to the top end thereof being pierced by the piercing tip 194 of the distal portion 188). In addition to the distal portion 188 of the dilator projection 184 being extended into the Y-injection site 166, the enlarged end region of the Y-injection site 166 is captured within the pitch barbs 248, thus preventing the movement thereof distally away from the adapter member 172 and removal of the distal portion 188 from therewithin. When the reseal member 220 is moved to the open position, fluid flows from the outlet passage 246 of the introducer device 244 into the Y-injection site 166 via the fluid passage 190 of the dilator projection 184. Though not shown in detail, the engagement of the injection site 160 to the neck of the bottle 168 occurs in the same manner as described in relation to the Y-injection site 166.

As seen in FIG. 17, the engagement of the injection site 160 to the tubular fluid line 164 is accomplished by initially removing the cover member 250 from the distal portion 188 of the dilator projection 184, and removing the adapter

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sleeve 254 from the connector cap 202. Thereafter, the distal portion 188 of the dilator projection 184 is slidably advanced into the lumen of the fluid line 164. Due to the tapered outer surface of the distal portion 188, the same is frictionally maintained within the fluid line 164 subsequent to being inserted into the lumen thereof. When the reseal member 220 is moved to the open position, fluid flows from the introducer device into the fluid line 164 via the fluid passage 190 of the dilator projection 184.

Additional modifications and improvements of the present invention may also be apparent to those skilled in the art. Thus, the particular combination of parts described and illustrated herein is intended to represent only certain embodiments of the present invention, and is not intended to serve as limitations of alternative devices within the spirit and scope of the invention.

What is claimed is:

1. A needleless injection site, comprising:

a housing comprising:

a main body portion defining proximal and distal ends and a bore extending axially therethrough; and
a tubular side arm portion in fluid communication with said main body portion;

a reseal member attached to the proximal end of the main body portion and extending into said bore, said reseal member having an elastically openable and closable aperture formed therein and normally residing in a closed position wherein the aperture is in a closed configuration;

said reseal member being deformable such that the application of distally directed pressure thereto will cause the reseal member to distally advance within the bore to an open position wherein the aperture assumes an open configuration, and the removal of the distally directed pressure therefrom will cause the reseal member to resiliently return to the closed position wherein the aperture assumes the closed configuration.

2. The injection site of claim 1 wherein said reseal member comprises:

a circularly configured proximal portion defining a top surface and having a flange formed about the periphery thereof for attaching the reseal member to the main body portion;

a cylindrically configured central portion defining a side surface and a bottom surface having a conically shaped notch formed therein, said aperture extending from the top surface of the proximal portion to the apex of the notch; and

a tubular distal portion, said distal portion being invertible and adapted to overlap the side surface of the central portion and apply a radially inward biasing force thereto when inverted which maintains the aperture in the closed configuration when no distally directed pressure is applied to the top surface of the proximal portion.

3. The injection site of claim 2 further comprising a lock ring for securing the reseal member to the proximal end of the main body portion, said flange being rigidly captured between said main body portion and said lock ring.

4. The injection site of claim 2 wherein said reseal member is fabricated from silicone.

5. The injection site of claim 1 wherein said main body portion defines an outer surface having Luer threads formed thereon adjacent the proximal end thereof.

6. A needleless injection site, comprising:

a housing comprising:

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a main body portion defining proximal and distal ends and a bore extending axially therethrough;

an elongate dilator projection formed on the proximal end of said main body portion and extending axially therefrom, said dilator projection defining a longitudinally extending fluid passage in fluid communication with said bore;

a connector cap attached to the proximal end of said main body portion, said connector cap defining a central opening into which said dilator projection extends; and

a tubular side arm portion in fluid communication with said main body portion;

a reseal member disposed within said opening, said reseal member having an elastically openable and closable aperture formed therein and normally residing in a closed position wherein the aperture is in a closed configuration, said dilator projection extending into said reseal member;

said reseal member being deformable such that the application of distally directed pressure thereto will cause the reseal member to distally advance within the opening to an open position wherein the aperture is forced over a portion of the dilator projection, and the removal of the distally directed pressure therefrom will cause the reseal member to resiliently return to the closed position wherein the aperture assumes the closed configuration.

7. The injection site of claim 6 wherein said reseal member is attached to said connector cap.

8. The injection site of claim 7 wherein said reseal member comprises:

a circularly configured proximal portion defining a top surface and having a flange formed about the periphery thereof for attaching said reseal member to the connector cap;

a cylindrically configured central portion defining a side surface and a bottom surface having an elongate, generally concave recess formed therein sized and configured to receive said dilator projection, said aperture extending from the top surface of the proximal portion to the apex of said recess; and

a tubular distal portion, said distal portion being invertible and adapted to overlap the side surface of the central portion and apply a radially inward biasing force thereto when inverted which maintains the aperture in the closed configuration when no distally directed pressure is applied to the top surface of the proximal portion.

9. The injection site of claim 8 further comprising a lock ring for securing the reseal member to the connector cap, said flange being rigidly captured between said connector cap and said lock ring.

10. The injection site of claim 8 wherein said reseal member is fabricated from silicone.

11. The injection site of claim 6 wherein said connector cap defines an outer surface having Luer threads formed thereon adjacent the central opening thereof.

12. The injection site of claim 6 wherein said main body portion normally resides in a first position within the connector cap, and is adapted to move distally relative to the connector cap to a second position therewithin when distally directed pressure is applied to the reseal member, and resiliently return to the first position when the distally directed pressure is removed from the reseal member.

13. The injection site of claim 12 wherein said main body

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portion includes a leaf spring molded thereon which is cooperatively engaged to the connector cap and adapted to bias the main body portion to the first position.

14. The injection site of claim 6 wherein said reseal member is cooperatively engaged to the dilator projection and disposed in abutting contact with the proximal end of the main body portion.

15. A needleless injection site comprising:

a housing comprising:

an adapter member defining proximal and distal ends and an interior chamber;

an elongate dilator projection formed on the proximal end of said adapter member, said dilator projection defining a proximal portion extending axially from the proximal end, a distal portion extending axially into the interior chamber and a longitudinally extending fluid passage in fluid communication with said interior chamber; and

a connector cap attached to said adapter member and defining a central opening, said adapter member being disposed within said connector cap, with the proximal portion of the dilator projection extending into said opening;

a reseal member disposed within said opening, said reseal member having an elastically openable and closable aperture formed therein and normally residing in a closed position wherein the aperture is in a closed configuration, the proximal portion of said dilator projection extending into said reseal member;

said reseal member being deformable such that the application of distally directed pressure thereto will cause the reseal member to distally advance within the opening to an open position wherein the aperture is forced over the proximal portion of the dilator projection, and the removal of the distally directed pressure therefrom will cause the reseal member to resiliently return to the closed position wherein the aperture assumes the closed configuration.

16. The injection site of claim 15 wherein said reseal member comprises:

a tubular proximal portion; and

a cylindrically configured distal portion defining top, bottom and side surfaces, and including an elongate, generally concave recess formed in the bottom surface thereof which is sized and configured to receive the proximal portion of the dilator projection, said aperture extending from the top surface to the apex of the recess; said proximal portion being invertible and adapted to overlap the side surface of the distal portion and apply a radially inward biasing force thereto when inverted which maintains the aperture in the closed configuration when no distally directed pressure is applied to the top surface of the distal portion.

17. The injection site of claim 16 wherein said reseal member is fabricated from silicone.

18. The injection site of claim 15 wherein said connector cap defines an outer surface having Luer threads formed thereon adjacent the central opening thereof.

19. The injection site of claim 15 wherein said adapter member normally resides in a first position within the connector cap, and is adapted to move distally relative the

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connector cap to a second position therewithin when distally directed pressure is applied to the reseal member, and resiliently return to the first position when the distally directed pressure is removed from the reseal member.

20. The injection site of claim 19 wherein said adapter member includes a leaf spring molded thereon which is cooperatively engaged to the connector cap and adapted to bias the adapter member to the first position.

21. The injection site of claim 15 wherein said reseal member is cooperatively engaged to the proximal portion of the dilator projection and disposed in abutting contact with the proximal end of the adapter member.

22. The injection site of claim 15 wherein the distal portion of the dilator projection has a tapered outer surface for facilitating the connection of the housing to a tubular fluid line, said housing being connected to the fluid line via the insertion of the distal portion of the dilator projection into the lumen of the fluid line, said distal portion being frictionally retained within the lumen subsequent to being inserted thereinto.

23. The injection site of claim 15 wherein said adapter member further comprises a tubular adapter sleeve slidably extensible over and frictionally maintainable on the distal portion of the dilator projection for facilitating the connection of the housing to a Luer connector, said housing being connected to the Luer connector via the insertion of the adapter sleeve into the lumen of the Luer connector, said adapter sleeve being frictionally retained within the lumen subsequent to being inserted thereinto.

24. The injection site of claim 23 wherein the distal portion of the dilator projection has a tapered outer surface and the adapter sleeve has a tapered bore extending longitudinally therethrough which is complimentary to the outer surface of the distal portion of the dilator projection for facilitating the frictional retention of the adapter sleeve thereon.

25. The injection site of claim 24 wherein the distal portion of the dilator projection includes an elongate rib formed on the outer surface thereof and the bore of the adapter sleeve defines an elongate slot therewithin which is sized and configured to receive the rib when the adapter member is slidably advanced over the distal portion of the dilator projection, the receipt of the rib into the slot being operable to prevent the rotation of the adapter sleeve upon the distal portion of the dilator projection.

26. The injection site of claim 23 wherein the adapter sleeve has a tapered outer surface for frictionally retaining the adapter sleeve within the lumen of the Luer connector subsequent to being inserted thereinto.

27. The injection site of claim 23 wherein said adapter member further defines a tubular lock region within the distal end thereof which is configured to engage the Luer threads of the Luer connector when the adapter sleeve is inserted into the lumen thereof.

28. The injection site of claim 27 wherein said lock region defines a plurality of Luer thread pitch barbs therewithin.

29. The injection site of claim 15 wherein said adapter member further defines a lock region within the distal end thereof for facilitating the connection of the housing to a Y-injection site, the housing being connected to the Y-injection site via the insertion of the Y-injection site into the

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lock region of the adapter member and the extension of the distal portion of the dilator projection into the Y-injection site.

30. The injection site of claim **29** wherein the lock region of the adapter member defines a plurality of Luer thread⁵ pitch barbs formed therewithin.

31. The injection site of claim **29** wherein said adapter member comprises:

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an upper section defining said dilator projection; and
a lower section rigidly attached to said upper section and defining said lock region, said upper and lower sections defining said interior chamber when attached to each other.

* * * * *

Exhibit B



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,772	12/08/2003	Steven C. Jepson	SMMDD-5128 REI	2213
29200 7590 11/30/2007 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER GRAY, PHILLIP A	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 11/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/730,772

Applicant(s)

JEPSON ET AL.

Examiner

Phillip Gray

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/21/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to communication of 10/05/2006. Currently claims 1-90 are pending and rejected below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-13, 15-19, 21-25, 27-45, 47-51 and 53-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayer (U.S. Patent Number 5,470,319). Mayer discloses a connector device (needleless injection site) for establishing a connection with a male Luer assembly, an assembly which includes a male luer tip (194) and annular flange (see 176/202 in figures 15,16,17), and a connector device comprising a housing (170) with an upper end opening (near 204) and a central first passageway (unnumbered but shown in figure 9 near 147 for example which fluid flows through and male luer is received), housing has a first constant diameter portion (top portion of housing in figure 15 for example), a constant diameter second portion larger then the first (lower portion of housing in figure 15 for example) and a third intermediate portions with a changing diameter (middle portion of housing in figure 15 for example). Mayer

discloses a stretched resealable valve (28, 122, or 220 for some example), which include a first portion to seal opening and upper surface that is wipable (see figures 9 and 10), a second portion (near 84 for example) and third portion (near 139 for example), and forth and split collar collapsing member (226 for example), with an annular space between extension portion and housing (note space near 106 and 90 as example in figure 9) and second passageway (unnumbered but shown in figure 9 near 84 for example which fluid flows through and male luer is received), and an opening (147) formed in the valve that when the luer tip is inserted said first portion and second portion elastically extend and form a seal and allow fluid to be injected into the second passageway without flowing into the annular space (see figures 10 and 15-17) and some fluid remains in the second passageway when the male luer tip is removed, and a bonding agent to attach (such as sonic bonding from the disclosure or element 52/60). Concerning claims 2-5, 10-12, 16-18, 22-25, 42-44, 48-50 the valve includes a septum with an annular skirt and annular channel formed by the skirt with a distal landing (see figures 3, 4, and 7). The elements disclosed in Mayer are fully capable of satisfying all structural, functional, spatial, and operational limitations in the claims, as currently written, and the rejection is made and proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 14, 20, 26, 46 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer. Mayer discloses the claimed invention except for a generally rectangular cross section in the proximate direction. It would have been an obvious matter of design choice to form the valve with a rectangular cross section in the proximate direction, since applicant has not disclosed that this cross section formation solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a circular cross section, and in the alternative it would be within the level of ordinary skill in the art to change the circular cross section to a rectangular cross section in order to limit the flow rate by decreasing the area of the cross section, (changing from a circle to rectangle). In cases like the present, where patentability is said to be based upon particular chosen dimensions or upon another variable recited within the claims, applicant must show that the chosen dimensions are critical. As such, the claimed dimensions appear to be an obvious matter of

engineering design choice and thus, while being a difference, does not serve in any way to patentably distinguish the claimed invention from the applied prior art. *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); *In re Kuhle*, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Further a change in the shape of a prior art device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 recites the limitation "a first portion", and "said extension portion" in the description of the resealable valve. There is insufficient antecedent basis for this limitation in the claim. It is unclear from the claim which "first portion" is being referred to, and how many "extension portions" there are. The claim is unclear in "...having a third extension portion attached to one of said extension portion and a lower surface of said radial portion and extending downward, a lower end portion of said extension portion attached...".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PAG

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons

Exhibit C



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,772	12/08/2003	Steven C. Jepson	SMMDD-5128 REI	2213
29200 7590 03/04/2008 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER GRAY, PHILLIP A	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 03/04/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No. 10/730,772	Applicant(s) JEPSON ET AL.	
	Examiner Phillip Gray	Art Unit 3767	

All participants (applicant, applicant's representative, PTO personnel):

- (1) Phillip Gray. (3) Jeffrey C. Nichols.
 (2) Robert W. Connors. (4) _____.

Date of Interview: 25 February 2008.

Type: a) ☐ Telephonic b) ☐ Video Conference
 c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
 If Yes, brief description: _____.

Claim(s) discussed: 1,27 and 85.

Identification of prior art discussed: MAYER (U.S. 5,470,319); LYNN.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Phillip Gray/
 Examiner, Art Unit 3767

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action. Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's attorneys kindly discussed the general nature of the application "Needless Connector" and what they feel are their novel improvements over the prior art thereof. Further applicant's attorneys discussed the claims and their scope as presently written. Examiner appreciated and agreed with the applicant's explanation and argument about how the "Needless Connector" invention's Leur Tip opening of the valve was different from the MAYER reference (and other prior art of record) of pushing or moving the opening of the valve to create a passageway, but that the claims could be further clarified to highlight the above difference. It is examiners position that MAYER currently does disclose all structural components and these elements satisfy all functional, spatial, structural and operational limitations in the claims as written. It was recommended that applicant amend the claims to greater define the aspects of the invention that they consider novel and reasons why this feature is not shown in the prior art and is nonobvious over the prior art of record.

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Exhibit D

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jepson et al.
Appl. No.: 10/730,772
Conf. No.: 2213
Filed: December 8, 2003
Title: NEEDLELESS CONNECTOR
Art Unit: 3767
Examiner: Phillip A. Gray
Docket No.: MDD-5128 REI (112713-596)

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE

Examiner:

In Response to the Office Action dated November 30, 2007, and the personal interview granted courteously to Applicants' representatives on February 25, 2008, please amend the above-identified patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 23 of this paper.

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards~~, said assembly including a male luer tip, ~~said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip~~, said connector device comprising:

a housing forming an upper end opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing, said housing including a first upper edge portion having an outside surface of generally constant first diameter, and a second lower portion spaced from said upper edge portion and having an outside surface of a generally constant second diameter, said second diameter being larger than said first diameter, said housing including a third intermediate portion extending from said distal edge portion to said second lower portion, said third intermediate portion having an outside surface with a changing diameter;

a resealable valve resiliently restrained relative to said housing, said valve including a first valve portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second ~~extension~~ valve portion integral with said first valve portion and extending generally vertically downward within said passageway from a lower surface of said first valve portion, said valve having a third ~~extension~~ valve portion ~~attached to extending from~~ one of said ~~extension~~ second valve portion and a lower surface of said ~~radial~~ first valve portion ~~and extending downward~~, a lower end portion of said ~~extension~~ third valve portion attached to said housing to form a sealed second passageway within said ~~extension~~ third valve portion, said ~~extension~~ third valve portion and said housing defining a ~~generally annular~~ space between said ~~extension~~ third valve portion and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first valve portion, said first valve portion and said second valve portion ~~elastically extend about~~ are forced radially open by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said ~~extension~~ third valve portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said ~~annular~~ space.

Claim 2 (currently amended) The connector device of claim 1 wherein said valve includes a septum having an annular skirt attached to said first valve portion, said skirt extending over and attached to an outside surface of said housing proximate said opening.

Claim 3 (original) The connector device of claim 2 wherein said septum includes an annular channel formed by said skirt and said first portion, a distal edge portion of said housing received in said channel.

Claim 4 (original) The connector device of claim 3 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 5 (original) The connector of claim 4 wherein the entire length of said landing is attached to said septum.

Claim 6 (original) The connector device of claim 5 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 7 (original) The connector device of claim 1 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 8 (currently amended) The connector device of claim 1 wherein said second ~~extension~~ valve portion is in a stretched configuration.

Claim 9 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards~~, said assembly including a male luer tip and ~~having a generally annular flange disposed generally about said male luer tip and defining a generally cylindrical space between said flange and said tip~~, said connector device comprising:

a housing forming an upper opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the generally cylindrical space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including,

a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable,

a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and

a third ~~extension~~ portion attached to said lower surface of said first portion and extending downward, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said ~~extension~~ third portion, said second portion extending within said second sealed passageway portion, said third ~~extension~~ portion and said housing defining a ~~generally annular~~ space between said ~~extension~~ third portion and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion ~~elastically extend about~~ are forcibly opened by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said ~~extension~~ third portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said ~~annular~~ space.

Claim 10 (currently amended) The connector device of claim 9 which includes a septum having an annular channel formed by ~~said skirt and~~ said first portion, a distal edge portion of said housing received in said channel.

Claim 11 (original) The connector device of claim 10 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 12 (original) The connector of claim 11 wherein the entire length of said landing is attached to said septum.

Claim 13 (original) The connector device of claim 12 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 14 (original) The connector device of claim 13 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 15 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards~~, said assembly including a male luer tip, ~~said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip~~, said connector device comprising:

a housing forming an upper end opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper

surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second ~~extension~~ portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third ~~extension~~ portion ~~attached to~~ extending from one of said second ~~extension~~ portion and a lower surface of said first portion ~~and extending downward~~, a lower end portion of said third ~~extension~~ portion attached to said housing to form a sealed second passageway, said valve and said housing defining a ~~generally annular~~ space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second ~~extension~~ portion ~~elastically extend about~~ are radially opened by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip, the attachment of said lower end portion of said third ~~extension~~ portion to said housing being such that fluid injected from said tip flows through said housing without flowing into said ~~annular~~ space.

Claim 16 (currently amended) The connector device of claim 15 which includes a septum having an annular channel formed by ~~said skirt and~~ said first portion, a distal edge portion of said housing received in said channel.

Claim 17 (previously presented) The connector device of claim 16 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 18 (previously presented) The connector of claim 17 wherein the entire length of said landing is attached to said septum.

Claim 19 (previously presented) The connector device of claim 18 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 20 (previously presented) The connector device of claim 15 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 21 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards~~, said assembly including a male luer tip ~~and having a generally annular flange disposed generally about said male luer tip and defining a generally cylindrical space between said flange and said tip~~, said connector device comprising:

a housing forming an upper opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the generally cylindrical space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and a third ~~extension~~ portion ~~attached to~~ extending from a lower surface of said second portion and ~~extending downward~~, a lower end portion of said third ~~extension~~ third portion attached to said housing to form a sealed second passageway within said ~~extension~~ third portion, at least portions of said valve and said housing defining a ~~generally annular~~ space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion into said second passageway portion, the luer tip opens said first portion and said second ~~portion elastically extend about the luer tip and form portion, forming~~ a radial seal about said luer tip, the attachment of said lower end portion of said third ~~extension~~ third portion to said housing being such that fluid injected from said tip flows through said housing without flowing into said ~~annular~~ space.

Claim 22 (currently amended) The connector device of claim 21 which includes a septum having an annular channel formed by said ~~skirt and said~~ first portion, a distal edge portion of said housing received in said channel.

Claim 23 (previously presented) The connector device of claim 22 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 24 (previously presented) The connector of claim 23 wherein the entire length of said landing is attached to said septum.

Claim 25 (previously presented) The connector device of claim 24 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 26 (previously presented) The connector device of claim 25 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 27 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards~~, said assembly including a male luer tip, ~~said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip~~, said connector device comprising:

a housing forming an upper end opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper

surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second ~~extension~~ portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third ~~extension~~ portion attached to said ~~extension~~ second portion and sealingly attached to said housing, at least a portion of said valve and said housing defining a ~~generally annular~~ space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion and within said second ~~passageway~~, ~~portion, the luer tip radially opens~~ said first portion and said second ~~extension~~ portion ~~elastically extend about the luer tip and form, forming a radial seal about said luer tip, the attachment of~~ said lower end portion of said ~~extension~~ third portion to said housing being such that when fluid is then injected from said tip, the fluid flows through said housing without flowing into said ~~annular~~ space.

Claim 28 (previously presented) The connector device of claim 27 wherein when the luer tip is inserted into the valve and fluid is injected through said tip upon removal of the luer tip, at least some fluid remaining in the second passageway is forced into the housing.

Claim 29 (currently amended) The connector device of claim 27 wherein the third ~~extension~~ portion ~~is connected to the second extension portion~~ extends downwardly within the housing.

Claim 30 (currently amended) The connector device of claim 27 wherein the third ~~extension~~ portion is integral with the second ~~extension~~ portion.

Claim 31 (currently amended) The connector device of claim 27 wherein the third ~~extension device~~ portion extends for a length greater than a diameter of the upper surface.

Claim 32 (currently amended) The connector device of claim 27 ~~including a fourth portion that is connected to the third extension~~ wherein the housing includes upper and lower pieces that crimp the third portion of the valve so as to be sealingly attached to said housing.

Claim 33 (currently amended) The connector device of claim 27 including a collapsing member located in the ~~annular~~ space.

Claim 34 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards~~, said assembly including a male luer tip, ~~said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip~~, said connector device comprising:

a housing forming an upper end opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second ~~extension~~ portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third ~~extension~~ portion attached to said second ~~extension~~ portion and extending downward, a lower end portion of said ~~extension~~ third portion attached to said housing to form a sealed second passageway within said ~~extension~~ third portion, said valve and said housing defining a ~~generally annular~~ space between said ~~extension~~ third portion and said valve;

a collapsing member connected to the third ~~extension~~ portion and located in the annular space; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, the luer tip pries said first portion and said second ~~extension~~ portion ~~elastically extend about the luer tip and form open, forming a radial seal about said luer tip and allow~~ allowing fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said ~~extension~~ third portion to

said housing being such that fluid injected into said second passageway flows through said housing without flowing into said ~~annular~~ space.

Claim 35 (previously presented) The connector device of claim 34 wherein upon removal of the luer tip, at least some of the fluid remaining in the second passageway is forced into the housing.

Claim 36 (previously presented) The connector device of claim 34 wherein the collapsing member is a split collar.

Claim 37 (currently amended) The connector device of claim 34 wherein the third ~~extension~~ portion is ~~connected to the second extension portion~~ extends downwardly within the housing.

Claim 38 (currently amended) The connector device of claim 34 wherein the third ~~extension~~ portion is integral with the second ~~extension~~ portion.

Claim 39 (currently amended) The connector device of claim 34 wherein the third ~~extension device~~ portion extends for a length greater than a diameter of the upper surface.

Claim 40 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards~~, said assembly including a male luer tip, ~~said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip~~, said connector device comprising:

a housing forming an upper end opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second ~~extension~~ portion extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third ~~extension~~ portion ~~attached to~~ extending from the second ~~extension~~ portion ~~and extending downward~~, a lower end portion of said third ~~extension~~ portion being so oriented with respect to said housing to form a sealed second passageway, said valve and said housing defining a ~~generally annular~~ space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second ~~extension~~ portion are elastically extend about opened by the luer tip and to form a radial seal about said luer tip ~~and allow~~, allowing fluid to be injected from said tip into said second passageway, the lower end portion of said ~~extension~~ third portion and said housing being oriented such that fluid injected into said second passageway flows through said housing without flowing into said ~~annular~~ space.

Claim 41 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards~~, said assembly including a male luer tip, ~~said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip~~, said connector device comprising:

a housing forming an upper end opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second portion integral with said first portion and extending generally

vertically downward within said passageway from a lower surface of said first portion, said ~~valve~~ second portion having a ~~portion~~ an end attached to said ~~second portion~~ and being attached to said housing such that said valve forms a sealed second passageway and ~~said valve portion~~ and said ~~housing~~ defining a ~~generally annular~~ space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said luer tip radially opens said first portion and said second portion ~~elastically extend about the luer tip and form, forming a radial~~ seal about said luer tip and ~~allow~~ allowing fluid to be injected from said tip, the attachment of said valve to said housing being such that fluid injected from said tip flows through said housing without flowing into said ~~annular~~ space.

Claim 42 (previously presented) The connector device of claim 41 which includes a septum having an annular channel formed by a skirt and said first portion, a distal edge portion of said housing received in said channel.

Claim 43 (previously presented) The connector device of claim 42 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 44 (previously presented) The connector of claim 43 wherein the entire length of said distal landing is attached to said septum.

Claim 45 (previously presented) The connector device of claim 44 wherein said connector includes a bonding agent to attach said outside surface of said housing and said distal landing to said septum.

Claim 46 (previously presented) The connector device of claim 41 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 47 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards~~, said assembly including a male luer tip ~~and having a generally annular flange disposed generally about said male luer tip and defining a generally cylindrical space between said flange and said tip~~, said connector device comprising:

a housing forming an upper opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the generally cylindrical space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and a third portion attached to a lower surface of said second portion, a portion of said third portion attached to said housing to form a sealed second passageway, at least portions of said valve and said housing defining a ~~generally annular~~ space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion into said second passageway portion, said first portion and said second portion are elastically extend about forced open by the luer tip ~~and form, forming~~ a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that fluid injected from said tip does not flow into said ~~annular~~ space.

Claim 48 (currently amended) The connector device of claim 47 which includes a septum having an annular channel formed by ~~said skirt and~~ said first portion, a distal edge portion of said housing received in said channel.

Claim 49 (previously presented) The connector device of claim 48 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 50 (previously presented) The connector of claim 49 wherein the entire length of said landing is attached to said septum.

Claim 51 (previously presented) The connector device of claim 50 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 52 (previously presented) The connector device of claim 51 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 53 (currently amended) A connector device for establishing a sealed connection with a male luer assembly ~~configured to conform to ISO standards, said assembly including a male luer tip, said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip, said~~ connector device comprising:

a housing forming an upper end opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a

third portion sealingly attached to said housing, at least a portion of said valve and said housing defining a ~~generally annular~~ space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second ~~extension~~ portion are elastically extend about opened by a radial force applied by the luer tip and form, forming a radial seal about said luer tip, the attachment of said third portion to said housing being such that when fluid is then injected from said tip, the fluid flows through said housing without flowing into said ~~annular~~ space.

Claim 54 (previously presented) The connector device of claim 53 wherein the third portion is integral with the second portion.

Claim 55 (currently amended) The connector device of claim 15 wherein said second ~~extension~~ portion is in a stretched configuration.

Claim 56 (currently amended) The connector device of claim 15 wherein said second ~~extension~~ portion is stretched so as to hinder buckling of said second ~~extension~~ portion when said luer tip is inserted downward into said opening.

Claim 57 (currently amended) The connector device of claim 15 wherein said second ~~extension~~ portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 58 (currently amended) The connector device of claim 21 wherein said second ~~extension~~ portion is in a stretched configuration.

Claim 59 (currently amended) The connector device of claim 21 wherein said second ~~extension~~ portion is stretched so as to hinder buckling of said second ~~extension~~ portion when said luer tip is inserted downward into said opening.

Claim 60 (currently amended) The connector device of claim 21 wherein said second ~~extension~~ portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 61 (currently amended) The connector device of claim 27 wherein said second ~~extension~~ portion is in a stretched configuration.

Claim 62 (currently amended) The connector device of claim 27 wherein said second ~~extension~~ portion is stretched so as to hinder buckling of said second ~~extension~~ portion when said luer tip is inserted downward into said opening.

Claim 63 (currently amended) The connector device of claim 27 wherein said second ~~extension~~ portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 64 (currently amended) The connector device of claim 34 wherein said second ~~extension~~ portion is in a stretched configuration.

Claim 65 (currently amended) The connector device of claim 34 wherein said second ~~extension~~ portion is stretched so as to hinder buckling of said second ~~extension~~ portion when said luer tip is inserted downward into said opening.

Claim 66 (currently amended) The connector device of claim 34 wherein said second ~~extension~~ portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 67 (currently amended) The connector device of claim 40 wherein said second ~~extension~~ portion is in a stretched configuration.

Claim 68 (currently amended) The connector device of claim 40 wherein said second ~~extension~~ portion is stretched so as to hinder buckling of said second ~~extension~~ portion when said luer tip is inserted downward into said opening.

Claim 69 (currently amended) The connector device of claim 40 wherein said second ~~extension~~ portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 70 (currently amended) The connector device of claim 41 wherein said second ~~extension~~ portion is in a stretched configuration.

Claim 71 (currently amended) The connector device of claim 41 wherein said second ~~extension~~ portion is stretched so as to hinder buckling of said second ~~extension~~ portion when said luer tip is inserted downward into said opening.

Claim 72 (currently amended) The connector device of claim 41 wherein said second ~~extension~~ portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 73 (currently amended) The connector device of claim 47 wherein said second ~~extension~~ portion is in a stretched configuration.

Claim 74 (currently amended) The connector device of claim 47 wherein said second ~~extension~~ portion is stretched so as to hinder buckling of said second ~~extension~~ portion when said luer tip is inserted downward into said opening.

Claim 75 (currently amended) The connector device of claim 47 wherein said second ~~extension~~ portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 76 (currently amended) The connector device of claim 53 wherein said second ~~extension~~ portion is in a stretched configuration.

Claim 77 (currently amended) The connector device of claim 53 wherein said second ~~extension~~ portion is stretched so as to hinder buckling of said second ~~extension~~ portion when said luer tip is inserted downward into said opening.

Claim 78 (currently amended) The connector device of claim 53 wherein said second ~~extension~~ portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 79 (currently amended) A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, ~~said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip,~~ said connector device comprising:

a housing forming an upper end opening and a ~~central~~ first passageway sized to receive the male luer tip, said housing having an upper end portion configured to ~~fit within the space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, said first ~~central~~ passageway extending from said opening in a downward direction within said housing, said housing including a first upper edge portion having an outside surface of generally constant first diameter, and a second lower portion spaced from said upper edge portion and having an outside surface of a generally constant second diameter, said second diameter being larger than said first diameter, said housing including a third intermediate portion extending between said first upper edge portion and said second portion, said third portion having an outside surface with a changing diameter;

a resealable valve resiliently restrained relative to said housing, said valve including a first valve portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second valve portion integral with said first valve portion and extending generally vertically downward within said passageway from a lower surface of said

first valve portion, said valve having a third valve portion ~~attached to~~ extending from one of said second valve portion and a lower surface of said first valve portion ~~and extending downward~~, a lower end portion of said third valve portion abutted against said housing to form a sealed second passageway ~~within said third portion~~, said third valve portion and said housing defining a space between said third valve portion and said housing; and

an opening formed in said valve such that when the luer tip is inserted into said opening in said housing and through said opening, said luer tip forcibly opens said first valve portion and said second valve portion ~~elastically extend about the luer tip and form~~, forms a radial seal about said luer tip and ~~allow~~ allows fluid to be injected from said tip into said second passageway, the abutment of said lower end portion of said third valve portion to said housing being such that fluid injected into said second passageway flows generally through said housing without flowing into said space.

Claim 80 (previously presented) The connector device of claim 79 wherein said third portion of said housing transitions from said first portion to said second portion of said housing.

Claim 81 (currently amended) The connector device of claim 79 wherein said lower end portion of said third valve portion is attached to said housing to form the sealed second passageway within said third portion.

Claim 82 (currently amended) The connector device of claim 79 wherein said space between said third valve portion and said housing is a generally annular space.

Claim 83 (currently amended) The connector device of claim 79 wherein at least a portion of said third portion of said valve prior to insertion of the luer tip widens towards its lower end portion.

Claim 84 (currently amended) The connector device of claim 79 wherein ~~at least a portion of said second portion of said valve is pushed against a wall forming said central first passageway when said luer tip is inserted into~~ the third valve portion extends generally downwardly within said housing.

Claim 85 (currently amended) A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, ~~said male luer tip encircled by an annular locking flange, said male luer tip and said flange defining a generally cylindrical space between said flange and said tip,~~ said connector device comprising:

a housing forming an upper end opening ~~and a central first passageway sized to receive the male luer tip, said housing having an upper end portion configured to fit within the space defined by~~ receive the male luer assembly when the male luer tip is inserted downward into said opening, ~~said first central passageway extending from said opening in a downward direction within said housing;~~

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending downward within said passageway housing ~~from a lower surface of said first portion,~~ said valve having a third portion sealingly abutted to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted into said opening in said housing, said first portion and said second portion ~~elastically extend about~~ are radially opened by the luer tip ~~and form, forming a radial seal about said luer tip,~~ the abutment of said third portion to said housing being such that when fluid is injected from said male luer tip, the fluid flows through said housing without flowing into said ~~annular~~ space.

Claim 86 (currently amended) The connector device of claim ~~79~~ 85 ~~wherein said third portion of said housing transitions from said first portion to said second portion of~~ wherein the third portion extends generally downwardly within said housing.

Claim 87 (currently amended) The connector device of claim ~~79~~ 85 wherein said ~~lower end portion of said third portion is attached to said housing to form the sealed second passageway within said third extension portion~~ seal.

Claim 88 (currently amended) The connector device of claim 79 85 wherein said space between said third portion and said housing is a generally annular space.

Claim 89 (currently amended) The connector device of claim 79 85 wherein at least a portion of said third portion of said valve prior to insertion of the luer tip widens towards its lower end portion.

Claim 90 (currently amended) The connector device of claim 79 85 wherein at ~~least a portion of said second portion of said valve is pushed against a wall forming said central~~ first passageway when the male luer tip is inserted into the housing the luer assembly conforms to ISO standards.

REMARKS

This Response is to the non-final Office Action dated November 30, 2007 and the personal interview granted courteously to Applicants' representatives on February 25, 2008. Claims 1 to 90 are pending and stand rejected. Claims 1, 2, 8 to 10, 15, 16, 21, 22, 27, 29 to 34, 37 to 41, 47, 48, 53, 55 to 79, and 81 to 90 have been amended herein without adding any new matter. Please charge Deposit Account No. for a Two Month Extension Of Time and any other fees deemed owed.

In the Office Action, claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,470,319 to Mayer ("*Mayer*"). Claims 7, 14, 20, 26, 46 and 52 were rejected under 35 U.S.C. § 103(a) as being obvious over *Mayer* alone. Claims 1 and 9 were rejected under 35 U.S.C. § 112, second paragraph, for lack of antecedent basis and other informalities.

Regarding the 35 U.S.C. § 112, second paragraph, rejection, claims 1 and 9 have been amended accordingly as shown above. Applicants respectfully submit that the amendments overcome the rejection.

In general, independent claims 1, 9, 15, 21, 27, 34, 40, 41, 47, 53, 79 and 85 have been clarified to be more readable, clear and focused. Accordingly, ISO standard and other particulars recited in the preamble have been removed. The space between the housing and the valve being "generally annular" has been eliminated as it is not needed. The word "extension" used to describe the valve portion has been removed in all places for clarity. In certain claims (e.g., claim 1 and certain dependents), the word "valve" has been added in front of the word "portion" to help distinguish between a valve portion and a housing portion. In certain claims (e.g., claim 1), the words "first", "second" and/or "third" are added to distinguish between the different valve portions. None of the above independent claim amendments has been made to overcome the art of record or to disclaim any subject matter regarding same.

Certain dependent claims have been amended to correct claim dependency (e.g., claims 86 to 90). Indeed, each of dependent claims 2, 8, 10, 16, 22, 29, 30 to 33, 37 to 39, 48, 55 to 78 and 81 to 90 has been amended for clarity or consistency with the independent claim from which it depends. None of the above dependent claim amendments has been made to overcome the art of record or to disclaim any subject matter regarding same.

In the interview, Examiner generally agreed that the principal of operation between Applicants' valve and that of *Mayer* and *Lynn* is different. Applicants respectfully submit that the present claims set forth the functional relationship between the first, second and third valve portions and the introduced male luer tip, so as to distinguish the claims patentably over the art of record.

In the interview, *Mayer* and an additional reference, namely, U.S. Patent No. 5,474,544 to *Lynn* ("*Lynn*") were discussed. It was discussed that both *Mayer* and *Lynn* show a valve that is translated or compressed by the luer to open a fluid pathway. The present claims however claim a different principal of operation, namely, one in which the luer tip is inserted into the valve to force or pry the valve portion open. It was discussed that such arrangement provides certain advantages, namely, less dead space and more effective use of the sealing capability of the valve material within a given housing size.

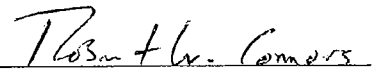
The claims are further clarified to specify that the resulting seal between the luer tip and the valve is a *radial* seal about the luer tip, which further and clearly distinguishes the claims over both *Mayer* and *Lynn*.

Applicants accordingly respectfully submit that this case should be reissued with the present claims.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY



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Phone: (312) 807-4214

Dated: April 22, 2008

Exhibit E



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,772	12/08/2003	Steven C. Jepson	SMMDD-5128 REI	2213
29200 7590 10/23/2008 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER GRAY, PHILLIP A	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 10/23/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)		
	10/730,772		JEPSON ET AL.		
	Examiner		Art Unit		
		Phillip Gray	3767		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 23 April 2008.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-90 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-90 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 4/23/2008.

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to communication of 4/23/2008. Currently claims 1-90 are pending and rejected below.

Response to Arguments

Applicant's arguments filed 4/23/2008 have been fully considered but they are not persuasive. Applicants argue that the claim language of **"the second valve portion is forced radially open by the luer tip"** is not shown in the Mayer reference. It is examiners position that when given a broad reading of the term "forced open" the Mayer reference does have a luer tip which forces open the second portion of the valve.

This is shown in figures 5, 10, 15, and 16 of the prior art Mayer. During examination, claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989); In re Prater, 415 F.2d 1393, 1404-1405, 162 USPQ 541, 550-51 (CCPA 1969). Under this broadest reasonable reading the Luer tip (near 58) does force the valve open radially (near 26). The elements disclosed in Mayer are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-13, 15-19, 21-25, 27-45, 47-51 and 53-90 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayer (U.S. Patent Number 5,470,319). Mayer discloses a connector device (needleless injection site) for establishing a connection with a male Luer assembly, an assembly which includes a male luer tip (194) and annular flange (see 176/202 in figures 15,16,17), and a connector device comprising a housing (170) with an upper end opening (near 204) and a central first passageway (unnumbered but shown in figure 9 near 147 for example which fluid flows through and male luer is received), housing has a first constant diameter portion (top portion of housing in figure 15 for example), a constant diameter second portion larger than the first (lower portion of housing in figure 15 for example) and a third intermediate portions with a changing diameter (middle portion of housing in figure 15 for example). Mayer discloses a stretched resealable valve (28, 122, or 220 for some example), which include a first portion to seal opening and upper surface that is wipable (see figures 9 and 10), a second portion (near 84 for example) and third portion (near 139 for example), and forth and split collar collapsing member (226 for example), with an annular space between extension portion and housing (note space near 106 and 90 as example in figure 9) and second passageway (unnumbered but shown in figure 9 near

84 for example which fluid flows through and male luer is received), and an opening (147) formed in the valve that when the luer tip is inserted said first portion and second portion elastically extend and form a seal and allow fluid to be injected into the second passageway without flowing into the annular space (see figures 10 and 15-17) and some fluid remains in the second passageway when the male luer tip is removed, and a bonding agent to attach (such as sonic bonding from the disclosure or element 52/60). Concerning claims 2-5,10-12, 16-18, 22-25, 42-44, 48-50 the valve includes a septum with an annular skirt and annular channel formed by the skirt with a distal landing (see figures 3, 4, and 7). The elements disclosed in Mayer are fully capable of satisfying all structural, functional, spatial, and operational limitations in the claims, as currently written, and the rejection is made and proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 3767

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 14, 20, 26, 46 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer. Mayer discloses the claimed invention except for a generally rectangular cross section in the proximate direction. It would have been an obvious matter of design choice to form the valve with a rectangular cross section in the proximate direction, since applicant has not disclosed that this cross section formation solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a circular cross section, and in the alternative it would be within the level of ordinary skill in the art to change the circular cross section to a rectangular cross section in order to limit the flow rate by decreasing the area of the cross section, (changing from a circle to rectangle). In cases like the present, where patentability is said to be based upon particular chosen dimensions or upon another variable recited within the claims, applicant must show that the chosen dimensions are critical. As such, the claimed dimensions appear to be an obvious matter of engineering design choice and thus, while being a difference, does not serve in any way to patentably distinguish the claimed invention from the applied prior art. *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); *In re Kuhle*, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Further a change in the shape of a prior art device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

Exhibit F



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jepson et al.
Appl. No.: 10/730,772
Conf. No.: 2213
Filed: December 8, 2003
Title: NEEDLELESS CONNECTOR
Art Unit: 3767
Examiner: Phillip A. Gray
Docket No.: MDD-5128 REI (112713-596)

Mail Stop After Final
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AFTER FINAL

Examiner:

In Response to the final Office Action dated October 23, 2008, Applicants respectfully request reconsideration of the pending rejections in light of the arguments set forth below:

A current listing of the Claims is provided for convenience beginning on Page 2.

Remarks begin on page 21 of this paper.

This listing of claims is provided for convenience:

Listing of Claims:

Claim 1 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing, said housing including a first upper edge portion having an outside surface of generally constant first diameter, and a second lower portion spaced from said upper edge portion and having an outside surface of a generally constant second diameter, said second diameter being larger than said first diameter, said housing including a third intermediate portion extending from said distal edge portion to said second lower portion, said third intermediate portion having an outside surface with a changing diameter;

a resealable valve resiliently restrained relative to said housing, said valve including a first valve portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second valve portion integral with said first valve portion and extending generally vertically downward within said passageway from a lower surface of said first valve portion, said valve having a third valve portion extending from one of said second valve portion and a lower surface of said first valve portion, a lower end portion of said third valve portion attached to said housing to form a sealed second passageway within said third valve portion, said third valve portion and said housing defining a space between said third valve portion and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first valve portion, said first valve portion and said second valve portion are forced radially open by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip into said second passageway, the attachment of

said lower end portion of said third valve portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.

Claim 2 (previously presented): The connector device of claim 1 wherein said valve includes a septum having an annular skirt attached to said first valve portion, said skirt extending over and attached to an outside surface of said housing proximate said opening.

Claim 3 (original): The connector device of claim 2 wherein said septum includes an annular channel formed by said skirt and said first portion, a distal edge portion of said housing received in said channel.

Claim 4 (original): The connector device of claim 3 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 5 (original): The connector of claim 4 wherein the entire length of said landing is attached to said septum.

Claim 6 (original): The connector device of claim 5 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 7 (original): The connector device of claim 1 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 8 (previously presented): The connector device of claim 1 wherein said second valve portion is in a stretched configuration.

Claim 9 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including,

a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable,

a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and

a third portion attached to said lower surface of said first portion and extending downward, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said third portion, said second portion extending within said second sealed passageway portion, said third portion and said housing defining a space between said third portion and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are forcibly opened by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of said third portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.

Claim 10 (previously presented): The connector device of claim 9 which includes a septum having an annular channel formed by said first portion, a distal edge portion of said housing received in said channel.

Claim 11 (original): The connector device of claim 10 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 12 (original): The connector of claim 11 wherein the entire length of said landing is attached to said septum.

Claim 13 (original): The connector device of claim 12 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 14 (original): The connector device of claim 13 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 15 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion extending from one of said second portion and a lower surface of said first portion, a lower end portion of said third portion attached to said housing to form a sealed second passageway, said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are radially opened by the luer tip and form a radial seal about said luer tip and allow fluid to be injected from said tip, the attachment of said lower end portion of said third portion to

said housing being such that fluid injected from said tip flows through said housing without flowing into said space.

Claim 16 (previously presented): The connector device of claim 15 which includes a septum having an annular channel formed by said first portion, a distal edge portion of said housing received in said channel.

Claim 17 (previously presented): The connector device of claim 16 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 18 (previously presented): The connector of claim 17 wherein the entire length of said landing is attached to said septum.

Claim 19 (previously presented): The connector device of claim 18 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 20 (previously presented): The connector device of claim 15 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 21 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper

surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and a third portion extending from a lower surface of said second portion, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said third portion, at least portions of said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion into said second portion, the luer tip opens said first portion and said second portion, forming a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that fluid injected from said tip flows through said housing without flowing into said space.

Claim 22 (previously presented): The connector device of claim 21 which includes a septum having an annular channel formed by said first portion, a distal edge portion of said housing received in said channel.

Claim 23 (previously presented): The connector device of claim 22 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 24 (previously presented): The connector of claim 23 wherein the entire length of said landing is attached to said septum.

Claim 25 (previously presented): The connector device of claim 24 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 26 (previously presented): The connector device of claim 25 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 27 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion attached to said second portion and sealingly attached to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion and within said second portion, the luer tip radially opens said first portion and said second portion, forming a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that when fluid is then injected from said tip, the fluid flows through said housing without flowing into said space.

Claim 28 (previously presented): The connector device of claim 27 wherein when the luer tip is inserted into the valve and fluid is injected through said tip upon removal of the luer tip, at least some fluid remaining in the second passageway is forced into the housing.

Claim 29 (previously presented): The connector device of claim 27 wherein the third portion extends downwardly within the housing.

Claim 30 (previously presented): The connector device of claim 27 wherein the third portion is integral with the second portion.

Claim 31 (previously presented): The connector device of claim 27 wherein the third portion extends for a length greater than a diameter of the upper surface.

Claim 32 (previously presented): The connector device of claim 27 wherein the housing includes upper and lower pieces that crimp the third portion of the valve so as to be sealingly attached to said housing.

Claim 33 (previously presented): The connector device of claim 27 including a collapsing member located in the space.

Claim 34 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

- a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

- a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion attached to said second portion and extending downward, a lower end portion of said third portion attached to said housing to form a sealed second passageway within said third portion, said valve and said housing defining a space between said third portion and said valve;

- a collapsing member connected to the third portion and located in the annular space; and

- an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, the luer tip pries said first portion and said second portion open, forming a radial seal about said luer tip and allowing fluid to be injected from said tip into said second passageway, the attachment of said lower end portion of

said third portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.

Claim 35 (previously presented): The connector device of claim 34 wherein upon removal of the luer tip, at least some of the fluid remaining in the second passageway is forced into the housing.

Claim 36 (previously presented): The connector device of claim 34 wherein the collapsing member is a split collar.

Claim 37 (previously presented): The connector device of claim 34 wherein the third portion extends downwardly within the housing.

Claim 38 (previously presented): The connector device of claim 34 wherein the third portion is integral with the second portion.

Claim 39 (previously presented): The connector device of claim 34 wherein the third portion extends for a length greater than a diameter of the upper surface.

Claim 40 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion extending from the

second portion, a lower end portion of said third portion being so oriented with respect to said housing to form a sealed second passageway, said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are elastically opened by the luer tip to form a radial seal about said luer tip, allowing fluid to be injected from said tip into said second passageway, the lower end portion of said third portion and said housing being oriented such that fluid injected into said second passageway flows through said housing without flowing into said space.

Claim 41 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said second portion having an end attached to said housing such that said valve forms a sealed second passageway defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said luer tip radially opens said first portion and said second portion, forming a radial seal about said luer tip and allowing fluid to be injected from said tip, the attachment of said valve to said housing being such that fluid injected from said tip flows through said housing without flowing into said space.

Claim 42 (previously presented): The connector device of claim 41 which includes a septum having an annular channel formed by a skirt and said first portion, a distal edge portion of said housing received in said channel.

Claim 43 (previously presented): The connector device of claim 42 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 44 (previously presented): The connector of claim 43 wherein the entire length of said distal landing is attached to said septum.

Claim 45 (previously presented): The connector device of claim 44 wherein said connector includes a bonding agent to attach said outside surface of said housing and said distal landing to said septum.

Claim 46 (previously presented): The connector device of claim 41 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 47 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, and a third portion

attached to a lower surface of said second portion, a portion of said third portion attached to said housing to form a sealed second passageway, at least portions of said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion into said second portion, said first portion and said second portion are elastically forced open by the luer tip, forming a radial seal about said luer tip, the attachment of said lower end portion of said third portion to said housing being such that fluid injected from said tip does not flow into said space.

Claim 48 (previously presented): The connector device of claim 47 which includes a septum having an annular channel formed by said first portion, a distal edge portion of said housing received in said channel.

Claim 49 (previously presented): The connector device of claim 48 wherein said distal edge portion forms a distal landing received in said channel, at least a portion of said distal landing being attached to said septum.

Claim 50 (previously presented): The connector of claim 49 wherein the entire length of said landing is attached to said septum.

Claim 51 (previously presented): The connector device of claim 50 wherein said connector includes a bonding agent to attach said outside surface of said housing and said landing to said septum.

Claim 52 (previously presented): The connector device of claim 51 wherein said second portion of said resealable valve is formed with a generally rectangular cross section in the proximate direction.

Claim 53 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending generally vertically downward within said passageway from a lower surface of said first portion, said valve having a third portion sealingly attached to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and through said first portion, said first portion and said second portion are elastically opened by a radial force applied by the luer tip, forming a radial seal about said luer tip, the attachment of said third portion to said housing being such that when fluid is then injected from said tip, the fluid flows through said housing without flowing into said space.

Claim 54 (previously presented): The connector device of claim 53 wherein the third portion is integral with the second portion.

Claim 55 (previously presented): The connector device of claim 15 wherein said second portion is in a stretched configuration.

Claim 56 (previously presented): The connector device of claim 15 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

Claim 57 (previously presented): The connector device of claim 15 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 58 (previously presented): The connector device of claim 21 wherein said second portion is in a stretched configuration.

Claim 59 (previously presented): The connector device of claim 21 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

Claim 60 (previously presented): The connector device of claim 21 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 61 (previously presented): The connector device of claim 27 wherein said second portion is in a stretched configuration.

Claim 62 (previously presented): The connector device of claim 27 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

Claim 63 (previously presented): The connector device of claim 27 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 64 (previously presented): The connector device of claim 34 wherein said second portion is in a stretched configuration.

Claim 65 (previously presented): The connector device of claim 34 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

Claim 66 (previously presented): The connector device of claim 34 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 67 (previously presented): The connector device of claim 40 wherein said second portion is in a stretched configuration.

Claim 68 (previously presented): The connector device of claim 40 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

Claim 69 (previously presented): The connector device of claim 40 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 70 (previously presented): The connector device of claim 41 wherein said second portion is in a stretched configuration.

Claim 71 (previously presented): The connector device of claim 41 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

Claim 72 (previously presented): The connector device of claim 41 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 73 (previously presented): The connector device of claim 47 wherein said second portion is in a stretched configuration.

Claim 74 (previously presented): The connector device of claim 47 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

Claim 75 (previously presented): The connector device of claim 47 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 76 (previously presented): The connector device of claim 53 wherein said second portion is in a stretched configuration.

Claim 77 (previously presented): The connector device of claim 53 wherein said second portion is stretched so as to hinder buckling of said second portion when said luer tip is inserted downward into said opening.

Claim 78 (previously presented): The connector device of claim 53 wherein said second portion is stretched during assembly of the connector and attached to said housing in a stretched configuration.

Claim 79 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening and a first passageway sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening, said first passageway extending from said opening in a downward direction within said housing, said housing including a first upper edge portion having an outside surface of generally constant first diameter, and a second lower portion spaced from said upper edge portion and having an outside surface of a generally constant second diameter, said second diameter being larger than said first diameter, said

housing including a third intermediate portion extending between said first upper edge portion and said second portion, said third portion having an outside surface with a changing diameter;

a resealable valve resiliently restrained relative to said housing, said valve including a first valve portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be easily wipeable, a second valve portion integral with said first valve portion and extending generally vertically downward within said passageway from a lower surface of said first valve portion, said valve having a third valve portion extending from one of said second valve portion and a lower surface of said first valve portion, a lower end portion of said third valve portion abutted against said housing to form a sealed second passageway, said third valve portion and said housing defining a space between said third valve portion and said housing; and

an opening formed in said valve such that when the luer tip is inserted into said opening in said housing and through said opening, said luer tip forcibly opens said first valve portion and said second valve portion, forms a radial seal about said luer tip and allows fluid to be injected from said tip into said second passageway, the abutment of said lower end portion of said third valve portion to said housing being such that fluid injected into said second passageway flows through said housing without flowing into said space.

Claim 80 (previously presented): The connector device of claim 79 wherein said third portion of said housing transitions from said first portion to said second portion of said housing.

Claim 81 (previously presented): The connector device of claim 79 wherein said lower end portion of said third valve portion is attached to said housing to form the sealed second passageway within said third portion.

Claim 82 (previously presented): The connector device of claim 79 wherein said space between said third valve portion and said housing is a generally annular space.

Claim 83 (previously presented): The connector device of claim 79 wherein at least a portion of said third portion of said valve prior to insertion of the luer tip widens towards its lower end portion.

Claim 84 (previously presented): The connector device of claim 79 wherein the third valve portion extends generally downwardly within said housing.

Claim 85 (previously presented): A connector device for establishing a sealed connection with a male luer assembly, said assembly including a male luer tip, said connector device comprising:

a housing forming an upper end opening sized to receive the male luer tip, said housing having an upper end portion configured to receive the male luer assembly when the male luer tip is inserted downward into said opening;

a resealable valve resiliently restrained relative to said housing, said valve including a first portion configured to seal said opening prior to insertion of said tip and having an upper surface radially extending across said opening, said upper surface being disposed and shaped to be wipeable, a second portion integral with said first portion and extending downward within said housing from said first portion, said valve having a third portion sealingly abutted to said housing, at least a portion of said valve and said housing defining a space between said valve and said housing; and

an opening formed in said valve such that when the luer tip is inserted into said opening in said housing, said first portion and said second portion are radially opened by the luer tip, forming a radial seal about said luer tip, the abutment of said third portion to said housing being such that when fluid is injected from said male luer tip, the fluid flows through said housing without flowing into said space.

Claim 86 (previously presented): The connector device of claim 85 wherein the third portion extends generally downwardly within said housing.

Claim 87 (previously presented): The connector device of claim 85 wherein said third portion is attached to said housing to form the seal.

Claim 88 (previously presented): The connector device of claim 85 wherein said space between said third portion and said housing is a generally annular space.

Claim 89 (previously presented): The connector device of claim 85 wherein at least a portion of said third portion of said valve prior to insertion of the luer tip widens towards its lower end portion.

Claim 90 (previously presented): The connector device of claim 85 wherein the luer assembly conforms to ISO standards.

REMARKS

This Response is to the final Office Action dated October 23, 2008. Claims 1 to 90 are pending and stand rejected. It is believed that no fee is due in connection with this Response, however, please charge Deposit Account No. 02-1818 for any fees deemed owed.

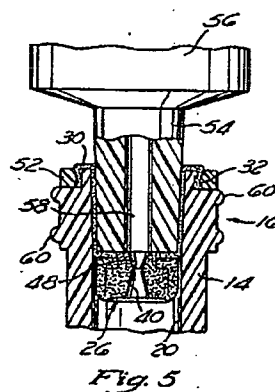
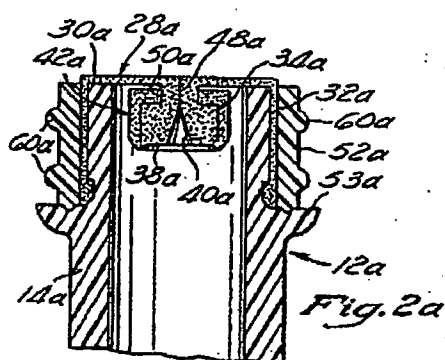
In the Office Action, claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,470,319 to Mayer ("*Mayer*"). Claims 7, 14, 20, 26, 46 and 52 were rejected under 35 U.S.C. § 103(a) as being obvious over *Mayer* alone.

As discussed in a February 25, 2008, personal interview and in the previous Response, *Mayer* teaches a valve that is translated or distally compressed by the luer to allow a fluid pathway to open by either stretching the valve open due to the attachment of the valve to the housing or forcing the valve downward to expose a fluid pathway opening in a dilator. The present claims however set forth a different principal of operation, namely, one in which the luer tip is inserted into the valve to force or pry open an opening in the valve portion. It was discussed that such arrangement provides certain advantages, namely, less dead space and more effective use of the sealing capability of the valve material within a given housing size. The claims also specify that the resulting seal between the luer tip and the valve is the tip extending through an upper portion of the valve thereby forming a *radial* seal about the luer tip, which further and clearly distinguishes the claims over *Mayer*.

The Office Action States that *Mayer* under a broad reading of the reference teaches "*the second valve portion is forced radially open by the luer tip*". As shown in detail below, the portion of the valve taken by the Office Action to be or teach the claimed "second valve portion" is either *already* open prior to contact by the luer and thus *cannot* be opened by application of the luer or is stretched or displaced radially open by interactions between the septum and other components of the device and not the luer tip. The Office Action also appears to ignore language found in the claims, such as, "the luer tip is inserted downward into said opening in said housing and through said first portion *and within said second portion*" [emphasis added] found in claim 27 and "an opening formed in said valve such that when the luer tip is inserted downward into said opening in said housing and *through said first portion into said second portion*" found in claim 47, for example. For these reasons and others set forth below, Applicants respectfully request reconsideration of the present claims.

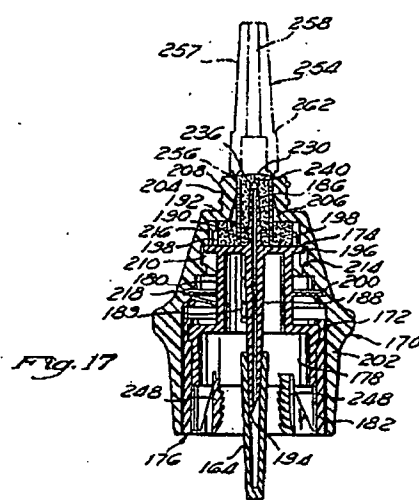
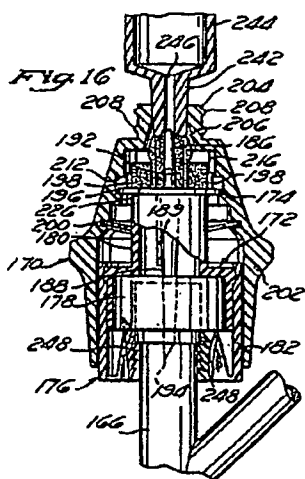
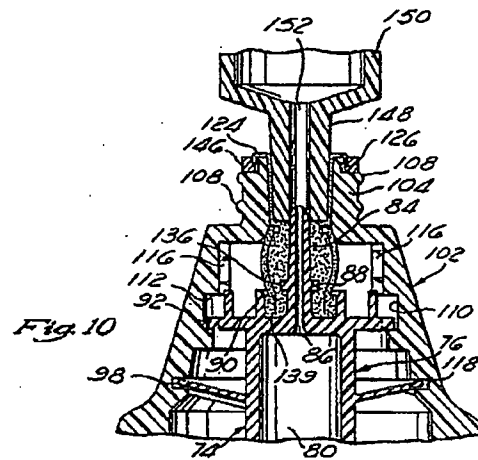
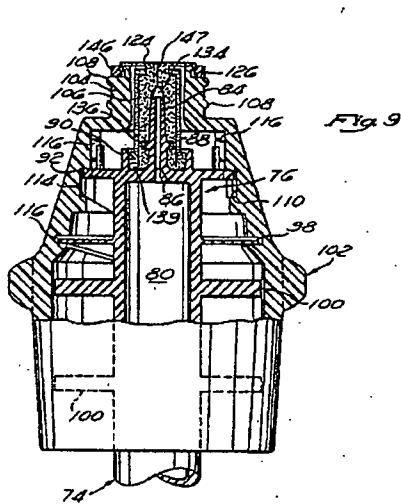
It is noted that throughout the Office Action, the Patent Office attempts to show anticipation by pointing to various combinations of elements over approximately three embodiments and does not focus on one embodiment to establish that all elements of a presented claim are found in that one embodiment. It is improper to borrow and steal elements from different embodiments of a reference to establish anticipation as confirmed in *Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1371 (C.A.F.C., October 20, 2008) (wrong to combine two separate protocols for anticipation even where only slight differences exist between them).

Mayer discloses three different valves or reseal members 26, 120 and 220. As shown in Figs. 1 to 5 (Figs. 2A and 5 incorporated herein for convenience), member 26 is clearly insufficient to teach the claims because it does not show any second or third valve portion attached to (as called for in claims 1, 9 15, 21, 27, 34, 41, 47, 53); or abutted against (as called for in claim 79, 85) the device housing. Nor does member 26 teach the member being connected to the housing such that fluid does not flow into a space defined between the valve and housing, as generally called for in the independent claims.



Figs. 6 to 10 and Figs. 14 to 17 disclose second and third embodiments (Figs. 9, 10, 16 and 17 incorporated herein for convenience). Neither of these embodiments teaches a valve having an opening such that a luer tip extends through any upper portion of the valve. Instead an entirely different operation of these valves is clearly set forth in the specification. Referring to Column 12, lines 64 to 67 and column 13 lines 1 to 9 for the embodiment shown in Figs. 6 to 10 and Column 17 lines 29 to 42 for the embodiment shown in Figs. 14 to 17, the tip of the introducer device applies distally directed pressure to the top surface of the proximal valve portion causing the reseal member to distally advance within the central opening, thereby

causing the aperture to be forced over the dilator wherein the proximal tip of the dilator projection protrudes from the top surface and is received in the outlet passage of the introducer device. Thus, the tip of the introducer device contacts the top surface throughout the activation sequence to apply a distally directed pressure, and there is no penetration of the tip through any portion of the reseal member. In fact the dilator *prevents* the male luer from extending at all *into* any portion of the valve, let alone *through* a portion of the valve. Finally there is no need for the tip to penetrate the valve as the passageway within the dilator extends upward within the tip opening. In addition, there is no disclosure or suggestion that anything but this dilator is forcing any radial opening of the passageway through the reseal member.



Regarding the embodiment shown in Figs. 6 to 10, which uses the disclosed reseal member 120, the Office action cites element number 84 as allegedly teaching the claimed "second portion" of the claimed "resealable valve". Element number 84 is actually the "dilator projection" of the embodiment of Figs. 6 to 10, but nevertheless shows an area of reseal member 120 that the Office Action cites as teaching the "second portion" of the claimed "resealable valve". In *Mayer* there is no disclosure or teaching of the claimed "resealable valve," which allows a luer to be (i) "*within said second portion*" of the valve as per claim 27 or (ii) moved "*into said second portion*" of the valve as per claim 47. Claims 27 and 47 accordingly recite additional patentable subject matter over *Mayer*. Moreover, it is respectfully submitted that due to the dilator, *Mayer* is physically incapable of having any portion of the introducer tip "inserted... within" (claim 27) or "inserted ... into" (claim 47) this element number 84 of the valve, nor is there any disclosure of a radial seal being formed about the luer tip by any portion of valve portion 84 as called for in claims 1, 9 and 15.

The application of *Mayer* is additionally misguided for the following reasons. First, piercing tip 194 of *Mayer* is not a luer tip as proposed in the Office Action at Page 3. Second, apparatuses 176 and 202 proposed to teach the claimed "annular flange" are actually part of two different structures of the embodiment of Figs. 14 to 17, neither of which alone or in combination is taught to provide or be an "annular flange".

Third, Fig. 9 used to teach the claimed "first central passageway" is for a *different embodiment* than that of Figs. 14 to 17 used to teach the luer tip and the housing 270. Fig. 9 has a different housing than housing 270, which may be incompatible with the other features of the device of Figs. 14 to 17.

Mayer also fails to teach numerous dependent claims. For example, claims 8, 55, 58, 61, 64, 67, 70, 73 and 74 further define the second valve portion to be in a stretched configuration. Portion 84 of reseal member 120 of *Mayer* is never in a stretched configuration.

Claims 56, 59, 62, 65, 68, 71, 74 and 77 further define the second portion of the valve to be stretched so as to hinder buckling of said second portion when the luer tip is inserted downward into said opening. Again, portion 84 of reseal member 120 of *Mayer* is never in a stretched configuration, let alone done so to prevent buckling.

Claims 57, 60, 63, 66, 69, 72, 75 and 78 further define the second portion of the valve to be stretched during assembly of the connector and attached to the housing in a stretched

configuration. *Mayer* does not reach these claims. The Office action makes no attempt to address these or any of the dependent claims listed above.

Claims 28 and 35 also specify that upon removal of the luer tip, at least some fluid remaining in the second passageway is forced into the housing. The Office action makes no attempt to address claims 28 and 35. In the absence of a Notice of Allowance, Applicants respectfully request that a specific rejection of each of the above claims be made of record.

Applicants accordingly respectfully request reconsideration of the anticipation rejection of claims 1 to 6, 8 to 13, 15 to 19, 21 to 25, 27 to 45, 47 to 51 and 53 to 90, and respectfully submit that the patentability of those claims renders moot the obviousness rejection of claims 7, 14, 20, 26, 46 and 52. For all of the above-listed reasons, Applicants accordingly respectfully submit that this case should be reissued with the present claims.

Respectfully submitted,

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